

EPA Reg. No. 352-904

PROCESSING REQUEST

Reg # 352-904

Decision # 434660

Description: Storage Stability and Corrosion Characteristics

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☐ Dated:

☒ Dated: 12/11/17

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer:

Menya Adams

Division:

BPPD

Phone:

703-347-8496

Date:

12/11/17



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

December 11, 2017

Ms. Patricia G. Devine
MANAGER, US REGISTRATION, DUPONT CROP PROTECTION
E.I. DuPont De Nemours and Company
CHESTNUT RUN PLAZA (CRP 720/2E5)
974 CENTRE RD.
WILMINGTON, DE 19805

Subject: E. I DuPont De Nemours and Company's Response to Storage Stability and Corrosion
Characteristics Terms of Registration

| Product Name (EPA Registration Number) | Application Date | EPA Receipt Date | Term(s) of Registration (Guideline No.) | OPP Decision Number |
|--|------------------|------------------|--|---------------------------|
| Refined Oil Nepeta Cataria 7% Liquid 352-904 | August 11, 2016 | August 12, 2016 | Storage Stability (Guideline No. 830.6317) Corrosion Characteristics (Guideline No. 830.6320) | 434660 |

Dear Ms. Devine:

On July 29, 2009 the U.S. Environmental Protection Agency (EPA) issued a Registration Notice for Refined Oil Nepeta Cataria 7% Liquid (EPA Reg. No. 352-904). Term #2 of the Registration Notice required that DuPont Chemical Solutions Enterprise provide acceptable studies to the EPA within 12 months.

On August 12, 2016, the EPA received data from E. I DuPont De Nemours and Company that responded to the data terms of the Registration Notice. In a memorandum dated September 07, 2017, the EPA rated the storage stability and corrosion characteristics (MRID Nos. 499934-01 & 481062-01) data as acceptable. Thus, you have fulfilled Term #2 of the July 29, 2009, Refined Oil Nepeta Cataria 7% Liquid Registration Notice.

The results indicate that for Refined Oil of Nepeta Cataria 7% Liquid formulation is stable and no physical changes and no corrosion evidence in the stored containers during the 12-month test period at storage condition 25°C and 50% relative humidity.

Page 2 of 2
EPA Reg. No. 352-904
OPP Decision No. 434660

If you have any questions, please contact Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

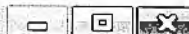
A handwritten signature in black ink, appearing to read "Andrew C. Bryceland". The signature is fluid and cursive, with a long horizontal stroke at the end.

Andrew Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure



Receipt for Section 3



S: 990396

Milestone Email:

Regulatory Type: Product Registration - Section 3

Resubmission: ☒ Yes ☐ No

Print Letter

Application Type: Amendment

Fee For Service: ☐ Yes ☒ No

Enter More Information

Billable: ☐ Yes ☒ No

Tracking

Company: 352 E. I. DU PONT DE NEMOURS AND COMPANY (S



Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91

Product #: 352-904 Product Name: REFINED OIL OF NEPETA CATARIA 7% LIQUI

Override#:

Me Too

Me Too Product

Section3:

Name:

Application Date: 11-Aug-2016



OPP Rec'd Date: 12-Aug-2016



Front End Date: 12-Aug-2016



Risk Manager Send Date: 12-Aug-2016



FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

Submission of response to cond data dated 9-1-2010

New Ingredient

Request Date:

New Ingredient

Received Date:

Form A: ☐

Signature Date:

Form B: ☐

Signature Date:

| Receipt Content | Des |
|-----------------|-----|
| Study | |
| III | |

View/Edit



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

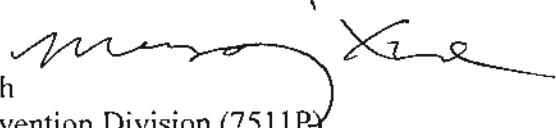
OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES


MEMORANDUM

DATE: September 7, 2017

SUBJECT: Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion Formulations (EPA Reg. #s: 352-902, 352-903 and 352-904), Containing 7% and 15% of Nepeta Cataria Oils (Active Ingredient), Respectively. Review of Storage Stability and Corrosion Characteristics

Decision Number: 434657, 434659 & 434660
Submission Nos.: 990394, 990395 & 990396
EPA Reg. #: 352-902, 352-903 & 352-904
Chemical Class: Biochemical
PC Code: 004801
Active Ingredient Tolerance Exemptions: 40 CFR 180.
MRIDs: 48106201 and 49993401

FROM: Manying Xue, Chemist /s/ 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

Through Russell S. Jones, Ph.D., Senior Biologist /s/ 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

Action Requested:

DuPont Crop Protection has submitted studies of storage stability and corrosion characteristics in support of registration of Refined Oil of Nepeta Cataria 7% Lotion (EPA Reg. #: 352-902), Refined Oil of Nepeta Cataria 7% Liquid (EPA Reg. #: 352-904) and Refined Oil of Nepeta Cataria 15% Lotion (EPA Reg. #: 352-903), containing 7 and 15% of Nepeta Cataria Oils (Active Ingredient), respectively.

BPPD has examined the submitted studies of storage stability and corrosion characteristics. The decisions are made to reflect the current OCSPP's policies.

Recommendations and deficiencies are noted below:

1. The submitted studies of storage stability and corrosion characteristics for Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion formulations (EPA Reg. #s: 352-902, 352-903, 352-904) are **ACCEPTABLE**. Results indicate that Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion formulations are stable and no physical changes and no corrosion evidence in the stored containers during the 12-month test period at storage condition of 25°C and 50% relative humidity.

Study Summaries

One-year storage stability and corrosion characteristics have conducted for Refined Oil of Nepeta Cataria 7% Lotion (EPA Reg. #: 352-902), Refined Oil of Nepeta Cataria 7% Liquid (EPA Reg. #: 352-904) and Refined Oil of Nepeta Cataria 15% Lotion (EPA Reg. #: 352-903). Samples of the test substances were packaged in bottles identical in materials and construction to the commercial containers in which the product is expected to be packaged. The containers used were glass and high density polyethylene (HOPE) for the formulation samples. The Technical and Manufacturing Grade samples were packaged in glass, HOPE, and aluminum.

Each container was identified with its contents by reference number. The samples were stored in a Caron 6010 environmental chamber at 25°C and 50% relative humidity for the intended storage duration (3 months, 6 months, and 12 months), and then removed from storage, weighed, visually inspected, and the test substance assayed.

Test Substance

Refined Oil of Nepeta Cataria 7% liquid formulation,
Refined Oil of Nepeta Cataria 15% liquid formulation,
Refined Oil of Nepeta Cataria 7% lotion formulation,
Refined Oil of Nepeta Cataria 15% lotion formulation.

Analytical Method

See CONFIDENTIAL APPENDIX for details.

Evaluations of Corrosion Characteristics

Corrosion characteristics were evaluated based upon changes in visual observations of the containers and closures following storage. At each observation time, the containers and closures were inspected inside and outside for perforations, dents, degradation of the seal or cap, and leaks. Two bottles were evaluated after storage for 3 months, 6 months, and 12 months. Six bottles were evaluated after storage for 12

months. Results are indicated in Tables 1-2.

Table 1. Analysis of Storage Stability of 7% and 15% of Nepeta Cataria Liquid Formulations and Physical observations of Corrosion characteristics (Diluted Samples)

| Test period (Month) | 7% of Nepeta Cataria Liquid AI Avg. Wt. ¹ & (% Recovery) | 7% of Nepeta Cataria Lotion AI Avg. Wt. & (% Recovery) | 15% of Nepeta Cataria Liquid AI Avg. Wt. & (% Recovery) | 15% of Nepeta Cataria Lotion AI Avg. Wt. & (% Recovery) | Physical Appearance |
|---------------------|--|---|--|--|--|
| 0 | 6.32 | 14.0 | 6.38 | 14.86 | No changes with visual observation for corrosion characteristics |
| 3 | 6.17 (97.63) | 13.76 (98.29) | 5.89 (92.32) | 13.17 (86.63) | |
| 6 | 6.85 (108.39) | 15.46 (110.43) | 6.81 (106.74) | 15.48 (104.17) | |
| 12 | 6.59, 6.50 (103.56) | 14.20, 15.46 (105.93) | 6.13, 6.08 (95.69) | 14.07, 14.41 (95.83) | |

¹ Each data point was calculated from six sample analysis.

Table 2. Analysis of Storage Stability of 7% and 15% of Nepeta Cataria Liquid Formulations and Physical observations of Corrosion characteristics (Prepared Samples)

| Test period (Month) | 7% of Nepeta Cataria Liquid AI Avg. Wt. ¹ & (% Recovery) | 7% of Nepeta Cataria Lotion AI Avg. Wt. & (% Recovery) | 15% of Nepeta Cataria Liquid AI Avg. Wt. & (% Recovery) | 15% of Nepeta Cataria Lotion AI Avg. Wt. & (% Recovery) | Physical Appearance |
|---------------------|--|---|--|--|--|
| 0 | 7.24 | 15.72 | 6.68 | 15.51 | No changes with visual observation for corrosion characteristics |
| 3 | 6.79 (93.40) | 15.28 (97.20) | 6.26 (93.71) | 13.73 (88.52) | |
| 6 | 7.29 (100.69) | 16.06 (102.16) | 6.66 (99.70) | 15.35 (98.97) | |
| 12 | 6.86, 6.77 (94.13) | 14.95, 14.20 (95.90) | 6.50, 6.45 (96.93) | 14.44, 14.87 (94.49) | |

¹ Each data point was calculated from six sample analysis.

Conclusion

The submitted studies of storage stability and corrosion characteristics for Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion formulations (EPA Reg. #s: 352-902, 352-903, 352-904) are **ACCEPTABLE**. Results indicate that for Refined Oil of Nepeta Cataria 7% and 15% Liquid and Lotion formulations are stable and no physical changes and no corrosion evidence in the stored containers during the 12-month test period at storage condition (25°C) and 50% relative humidity.

cc: M.Adams; BPPD Chron File; OHAD/ARS

M. Xue, BPPD, 09/7/2017

~~CONFIDENTIAL APPENDIX~~Analytical Method

Gas Chromatography (GC) utilizing a Flame Ionization Detector (FID) was used in these analyses. The samples to be analyzed were the refined oil of Nepeta cataria, also called Hydrogenated Catnip Oil (HCO) made up in either a liquid or a lotion formulation. The methods E108324-119, "Gas Chromatograph Method for the analysis of Hydrogenated Catnip Oil (HCO) in Formulations" and E108324-122, "Gas Chromatograph Method for the analysis of Hydrogenated Catnip Oil (HCO)" were followed for these analyses.

A solution of the formulation sample containing a known amount of the internal standard, 1,2-dibromobenzene, is analyzed by gas chromatography (GC) for the weight percent of each of the active ingredients in the liquid or lotion formulations or in the Technical and Manufacturing Grade, employing a DB-FFAP column and Flame Ionization Detector (FID). The weight percent of each component is determined by comparisons to calibration curves (peak area ratio vs. amount ratio) prepared from the analysis of standard solutions.

The sample preparation for the liquids consisted of accurately weighing three separate portions of the sample from a given container and mixing with an appropriate amount of Internal Standard Solution. For the lotions, three separate portions were accurately weighed, mixed with an appropriate amount of Internal Standard Solution, and filtered into a sample vial. These sample preparations, called "as prepared" or "neat" were analyzed directly using the GC techniques. These sample preparations were also diluted (1-part test material plus 4 parts solvent for the 7% formulations and 1 part test material plus 9 parts solvent for the 15% formulations) and analyzed using the GC techniques. These sample preparations were called "diluted".

Thus, for a 7% liquid formulation, there were three "neat" samples and three "diluted" samples obtained from any given container. There were a similar number of samples for the other ethanoic liquid and lotion formulations.

The reported results are the average of duplicate analyses of triplicate samples. Standard solutions were prepared from analytical reference standards. The Analytical Standards for analysis of samples were:

| | |
|-------------------------|-------|
| Trans-cis Nepetalactone | 98% |
| Dihydronepetalactone 1 | 99% |
| Nepetalic Acid 2 | 85% |
| Pulegic Acid 1B | 96% |
| Beta-Caryophyllene | 99.5% |
| 1,2-Dibromobenzene | 98% |

Sample Calculation Using Agilent (Hewlett Packard) ChemStation

The chromatographic data processing software of the ChemStation uses peak areas of each component analyzed and an internal standard, 1,2-dibromobenzene, to determine the concentration of the samples. Standard solutions containing known amounts of each component to be analyzed and 1,2-dibromobenzene are first analyzed to create a calibration. The calibration points are constructed by calculating an amount ratio and an area ratio for each level in the calibration table. An equation for the curve through the calibration points is then calculated using linear least squares, and the slope is determined, with the intercept set to zero.



DuPont Crop Protection
 Stine-Haskell Research Center
 P.O. Box 30
 Newark, DE 19714-0030

August 11, 2016

VIA FEDERAL EXPRESS

Fee For Service: No Fees are proposed for this action, as none are required to submit studies.

Ms. Linda Hollis
 Biopesticides and Pollution Prevention Division (BPPD)
 Document Processing Desk
 U.S. Environmental Protection Agency
 Office of Pesticide Programs (7504P)
 One Potomac Yard
 2777 S. Crystal Drive
 Arlington, VA 22202

Subject: Submission of Response to Storage Stability & Corrosion Characteristics Decision #434656 (dated 01-September-2010) for

Refined Oil of *Nepeta cataria* technical; EPA Reg. 352-901 (Formerly 71654-20)
 Refined Oil of *Nepeta cataria* 7% Lotion; EPA Reg. No. 352-902 (Formerly 71654-21)
 Refined Oil of *Nepeta cataria* 15% Lotion; EPA Reg. No. 352-903 (Formerly 71654-23)
 Refined Oil of *Nepeta cataria* 7% Liquid; EPA Reg. No. 352-904 (Formerly 71654-24)
 Refined Oil of *Nepeta cataria* 15% Liquid; EPA Reg. No. 352-905 (Formerly 71654-25)

Dear Ms. Hollis:

In May of 2014, the above listed products were transferred from company # 71654 (DuPont Chemical Solutions Enterprise) to company # 352 (DuPont Crop Protection).

In the process of reviewing the products, it was discovered that in September of 2010, company # 71654 received an evaluation of the Storage Stability study (MRID 48106201) submitted in response to the terms and conditions of registration as issued December 4, 2008. This study (OPPTS 830.6317 and 830.6320) was classified as UNACCEPTABLE BUT UPGRADABLE.



DuPont Crop Protection
Stine-Haskell Research Center
P.O. Box 30
Newark, DE 19714-0030

DuPont Crop Protection has determined that no response to this communication was ever submitted by company #71654 prior to the transfer. Therefore, we submit herein a position paper identified as DuPont-47312 in response to the three items identified in the communication to Company # 71654 as per Decision #434656.

A data transmittal and three copies of the following position paper are enclosed:

| | |
|--------------|--|
| DuPont-47312 | Refined Oil of <i>Nepeta Cataria</i> : Response to Decision # 434656 (Storage Stability and Corrosion Characteristics (MRID 48106201)) |
|--------------|--|

Please feel free to contact me at (302) 451-4525 if you have any questions regarding this submission.

Sincerely,

Bonnie J Bieber
U.S. Product Registration Specialist

DATA TRANSMITTAL DOCUMENT

Refined Oil of Nepeta Cataria

Name and Address of Submitter:

E.I. DuPont de Nemours and Company
1090 Elkton Road P.O. Box 30
Newark, DE 19714

Phone (302) 451-4525 (Bonnie J Bieber)

Regulatory Action in Support of Which this Package is Submitted:

Information Submitted in support of continued registration of Refined Oil of *Nepeta cataria*

Product Name:

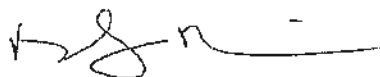
Refined Oil of Nepeta cataria technical; EPA Reg. 352-901 (Formerly 71654-20)
Refined Oil of Nepeta cataria 7% Lotion; EPA Reg. No. 352-902 (Formerly 71654-21)
Refined Oil of Nepeta cataria 15% Lotion; EPA Reg. No. 352-903 (Formerly 71654-23)
Refined Oil of Nepeta cataria 7% Liquid; EPA Reg. No. 352-904 (Formerly 71654-24)
Refined Oil of Nepeta cataria 15% Liquid; EPA Reg. No. 352-905 (Formerly 71654-25)

Transmittal Date: August 11, 2016

List of Submitted Studies:

| <u>Data Requirement</u> | <u>Doc Number</u> | <u>Study Title</u> | <u>MRID</u> |
|-------------------------|-------------------|--|-----------------|
| NA | DuPont-47312 | Refined Oil Of <i>Nepeta Cataria</i> : Response To Decision # 434656 (Storage Stability and Corrosion Characteristics (MRID 48106201)) | 49993401 |

Submitter:



Date:

11- AUG-2016

Bonnie J Bieber

U.S. Product Registration Specialist

Company Name: E.I. du Pont de Nemours and Company

PROCESSING REQUEST

Reg # 352-904 Decision # 522875

Description: Amendment to Sfrnge and
disposal Statement, Add marketing Claims,
And make minor formatting changes

Electronic Label & Letter
(see PPLS):

OR

Non Electronic
Label & Letter
(Scanning required):

☒ Dated: 10/26/16

☐ Dated:

Only one label type should be selected

Other Materials Sent (see jacket):

☐ New CSF(s) Dated:

☐ Other:

File this coversheet and attached materials in the jacket. It must be well organized and clipped together, NOT STAPLED. Then give the jacket with the coversheet and materials to staff in the Information Services Center (ISC) (Room S-4900). If a jacket is full or only available as an image, please file materials in a new jacket and bring it down to the (ISC). For further information please call 703-605-0716.

Reviewer: M. Enyon Adams

Division: BPPD

Phone: 703-347-8496

Date: 10/26/16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

October 26, 2016

Bonnie J. Bieber
Product Registration Specialist
DuPont Crop Protection
Stine-Haskell Research Center
1090 Elkton Road (S300/431)
Newark, DE 19711

Subject: Non-PRIA (Pesticide Registration Improvement Act) Labeling Amendment – Amend the storage and disposal statement, add marketing language and make minor formatting changes.
Product Name: Refined Oil of *Nepeta cataria* 7% Liquid
EPA Registration Number: 352-904
Application Date: October 17, 2016
OPP Decision Number: 522875

Dear Ms. Bieber:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 CFR § 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or

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EPA Reg. No. 352-904
OPP Decision No. 522875

misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

If you have any questions, please contact Ms. Menyon Adams of my team by phone at (703) 347-8496 or via email at adams.menyon@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Andrew C. Bryceland', with a stylized flourish at the end.

Andrew C. Bryceland, Team Leader
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division (7511P)
Office of Pesticide Programs

Enclosure



Refined Oil of *Nepeta cataria* 7% Liquid

INSECT REPELLENT LIQUID

Insect Repellent Pump-Spray[OPT]

| <i>Active Ingredients</i> | <i>By Weight</i> |
|--------------------------------------|------------------|
| Refined Oil of <i>Nepeta cataria</i> | 7.0% |
| <i>Other Ingredients</i> | 93.0% |
| TOTAL | 100.0% |

EPA Reg. No. 352-904

EPA Est. No. _____

Nonrefillable Container

Net: _____

E. I. du Pont de Nemours and Company
Chestnut Run Plaza, 974 Centre Road
Wilmington, DE 19805

ACCEPTED

10/26/2016

Under the Federal Insecticide, Fungicide,
and Rodenticide Act as amended, for the
pesticide registered under
EPA Reg. No. 352-904

**KEEP OUT OF REACH OF CHILDREN
WARNING**

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes: Hold eye open and rinse slowly and gently with water for 15-20 minutes. Remove contact lenses, if present, after 5 minutes, then continue rinsing eye. Call a Poison Control Center or doctor for further treatment advice.

If Swallowed: Call Poison Control Center or doctor immediately for treatment advice. Have person sip a glass of water if able to swallow. Do not induce vomiting unless told to do so by the poison control center or doctor. Do not give anything by mouth to an unconscious person.

PRECAUTIONARY STATEMENTS HAZARD TO HUMANS AND DOMESTIC ANIMALS WARNING

Causes substantial but temporary eye injury. Do not get in eyes or on clothing. Wash thoroughly with soap and water after handling and before eating, drinking, chewing gum, using tobacco or using the toilet. Remove and wash contaminated clothing before reuse.

HOTLINE NUMBER

Have the product container or label with you when calling a poison control center or doctor, or going for treatment. For emergency information on this pesticide product (including health concerns, medical emergencies, or pesticide incidents), call the poison control center at 1-800-222-1222. For non-emergency information concerning this product, call the National Pesticides Information Center (NPIC) at 1-800-858-7378 (NPIC Web site: www.npic.orst.edu)

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Repellency – Repels mosquitoes for up to 4 hours and black flies for up to 7 hours.

Do not allow children to handle the product or apply it to themselves. If used on the face, spray/dispense on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Dispense/Spray apply a small amount of liquid directly onto skin. Spread uniformly to completely cover any exposed skin surface. Use sparingly on face and avoid contact with eyes. Reapply after 4 -6 hours (or as needed). When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin. After returning indoors, wash treated skin with soap and water or bathe. Also wash clothing before wearing it again.

PHYSICAL AND CHEMICAL HAZARDS

FLAMMABLE. Keep away from Heat and Open Flame.

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal.

PESTICIDE STORAGE: Store away from children

PESTICIDE DISPOSAL: Do not contaminate water, food or feed by storage or disposal. Never place unused product down any indoor or outdoor drain.

CONTAINER HANDLING:

Nonrefillable container. Do not reuse or refill this container. If empty: Offer for recycling if available or discard in a sanitary landfill. If partly filled: Call your local solid waste agency for disposal instructions.

(NOTE TO REVIEWER: All claims in this section are optional)

- Mosquito repellent
- Blackfly repellent
- Repels mosquitoes
- Repels blackflies
- Effective protection from mosquitoes, and blackflies
- Effectively repels mosquitoes and blackflies
- (Effective) protection (from a range of mosquitoes and blackflies)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis)
- Works great on blackflies
- Protection (from bites) from blackflies (for the whole family)
- Protection for people on the go
- Protection that fits your lifestyle
- Protects from mosquitoes for up to 4 hours and (blackflies) (for up to 7 hours)
- Apply every 4-6 hours (or as needed)
- Repels mosquitoes for up to 4 hours and blackflies for up to 7 hours
- (Smart) Outdoor protection (from annoying (mosquitoes) for up to 4 hours and (black flies) (for up to 7 hours)
- Repels flies (too!)
- Keeps (bugs) (mosquitoes), off (your family)
- Guards the whole family (safely)
- Protection that fits your (active) lifestyle
- Protect(s) your family at dusk and dawn
- An effective insect repellent
- Protection during outdoor activities
- (Sport) (Active) (Outdoor) formula
- Outdoor mosquito and blackfly protection for play and on the go
- For yardwork and camping
- Protects during work, play or recreation
- Contains (a) plant-based repellent
- Plant based repellent repels (mosquitoes) for up to 4 hours (and) (blackflies) for (up to 7 hours)
- Contains plant extracts
- Contains the insect repellent found in (catmint) (catnip) (oil)
- (Plant based) (insect repellent without trade offs)

- Always carry (product name)
- For playing and relaxing outdoors
- Not oily, greasy or sticky
- No added fragrance
- Contains no dyes (or added fragrances)
- No chemical odor
- No synthetic odor
- No unpleasant odor
- Leaves pleasant feeling on skin
- Won't stain
- (Readily) (Easily) washed off
- Won't harm plastics
- Specially formulated to (feel) (and) (smell) better on your skin
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula
- No residue on skin
- (it's) pleasant smelling
- feel's comfortable
- DEET free
- Non DEET
- Non synthetic
- Readily washed off
- New!
- Repels (mosquitoes)(and) (blackflies)
- Repels mosquitoes that may carry (West Nile) (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) encephalitis (for up to 4 hours)
- Provides protection from mosquitoes for up to 4 hours
- up to 4 hour mosquito repellent; up to 7 hour blackfly repellent
- up to 4 hour mosquito protection; up to 7 hour blackfly protection
- (Up to) 4 hours of (effective) mosquito protection
- (Up to) 4 hours of protection from mosquitoes. Also (protects against) (works on) (repels) (.) (and) (blackflies) for up to 7 hours
- Protects for (up to) 4 hours against (mosquitoes) and for up to 7 hours against blackflies
- (Protects against) (Fights off) (Repels) (Works on) (mosquitoes)(.) (and) (blackflies)
- Protects against mosquitoes and (black flies)
- Long-lasting protection against (mosquitoes)(.) and (blackflies)
- Effective protection from mosquitoes
- Effective protection from blackflies
- Stay protected for up to 4 hours (from) (mosquitoes)(.) and for up to 7 hours from (blackflies)
- Stay protected for up to 4 hours from mosquitoes that may carry (West Nile) (St. Louis) (Eastern equine) (Western equine) (LaCrosse) (Cache Valley) encephalitis
- Proven protection from mosquitoes
- Mosquito protection (for up to 4 hours)
- Biting (mosquito), and, (black fly) protection that you can feel confident will last up to 4 hours for mosquitos and 7 hours for blackflies
- Repels mosquitoes (for up to 4 hours)
- Repels blackflies (for up to 7 hours)
- Easy to (Use) (Apply)
- For (hiking) (fishing) (hunting) (camping) (backpacking)
- Relax and enjoy the (outdoors)(.) (the great outdoors)(.) (backyard)(.) (outside)(.) (park)(.) (woods/forest) with up to 4 hours of protection against (mosquitoes) and up to 7 hours protection against (blackflies)
- Portable repellent protection
- Comfortable feel with no chemical (odor)(smell)
- Comfortable feel with pleasant smell
- Long-lasting
- Contains Refined Oil of *Nepeta cataria*
- Essential oil based repellent, not a synthetic chemical.

- Plant based essential oil insect repellent.
- Essential oil insect repellent with up to 4 hours of effective protection [against] [mosquitoes] [and] up to 7 hours of protection against blackflies
- Insect repellent with up to 4 hours of effective protection (against mosquitoes) and up to 7 hours against (blackflies)
- An essential oil repellent that protects against mosquitoes that may carry West Nile virus
- Repels mosquitoes that may carry West Nile Virus and Encephalitis
- Effective mosquito repellent
- Repels mosquitoes for up to 4 hours, which may carry West Nile Virus and Encephalitis
- Plant based, essential oil that repels mosquitoes for up to 4 hours
- A plant based insect repellent with up to 4-7 hours of effective protection
- Good for people
- Protects people
- Produced from a renewable resource

D - 1941 102616

LIMITATION OF WARRANTY AND LIABILITY

NOTICE: Read this Limitation of Warranty and Liability Before Buying or Using This Product. DuPont will not be responsible for losses or damages resulting from the use of this product in any manner not specifically directed by DuPont. User assumes all risks associated with such non-directed use. If the Terms Are Not Acceptable, Return the Product at Once, Unopened, and the Purchase Price Will Be Refunded.

It is impossible to eliminate all risks associated with the use of this product. Such risks arise from weather conditions, soil factors, off target movement, unconventional farming techniques, presence of other materials, the manner of use or application, or other unknown factors, all of which are beyond the control of DuPont. These risks can cause: ineffectiveness of the product, crop injury, or injury to non-target crops or plants. **WHEN YOU BUY OR USE THIS PRODUCT, YOU AGREE TO ACCEPT THESE RISKS.**

DuPont warrants that this product conforms to the chemical description on the label thereof and is reasonably fit for the purpose stated in the Directions for Use, subject to the inherent risks described above, when used in accordance with the Directions for Use under normal conditions.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, DUPONT MAKES NO OTHER EXPRESS OR IMPLIED WARRANTY OF FITNESS OR OF MERCHANTABILITY OR ANY OTHER EXPRESS OR IMPLIED WARRANTY. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, IN NO EVENT SHALL DUPONT OR SELLER BE LIABLE FOR ANY INCIDENTAL, CONSEQUENTIAL OR SPECIAL DAMAGES RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT. BUYER'S OR USER'S BARGAINED-FOR EXPECTATION IS CROP PROTECTION. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER AND THE EXCLUSIVE LIABILITY OF DUPONT OR SELLER, FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY OR CONTRACT, NEGLIGENCE, TORT OR STRICT LIABILITY), WHETHER FROM FAILURE TO PERFORM OR INJURY TO CROPS OR OTHER PLANTS, AND RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT, OR AT THE ELECTION OF DUPONT OR SELLER, THE REPLACEMENT OF THE PRODUCT.

To the extent consistent with applicable law that allows such requirement, DuPont or its Ag Retailer must have prompt notice of any claim so that an immediate inspection of buyer's or user's growing crops can be made. Buyer and all users shall promptly notify DuPont or a DuPont Ag Retailer of any claims, whether based on contract, negligence, strict liability, other tort or otherwise, or be barred from any remedy.





This Limitation of Warranty and Liability may not be amended by any oral or written agreement.

For product information call: 1-888-6-DUPONT [1-888-638-7668]

Internet address: <http://cropprotection.dupont.com/>

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All rights reserved.

| | |
|---|--|
| Create/E... Collections Utilities Query T... Portal Help Exit | |
| S: 993712 | Milestone Email: <input type="text"/> |
| Regulatory Type: Product Registration - Section 3 | Resubmission: <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Application Type: Amendment | Fee For Service: <input type="radio"/> Yes <input checked="" type="radio"/> No |
| Company: 352 E. I. DU PONT DE NEMOURS AND COMPANY (S | Billable: <input type="radio"/> Yes <input checked="" type="radio"/> No |
| | V |
| Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91 | |
| Product #: 352-904 | Product Name: REFINED OIL OF NEPETA CATARIA 7% LIQUI |
| Override#: <input type="text"/> | |
| Me Too Section3: <input type="text"/> | Me Too Product Name: <input type="text"/> |
| Application Date: 17-Oct-2016  | OPP Rec'd Date: 19-Oct-2016  |
| Front End Date: 19-Oct-2016  | Risk Manager Send Date: 20-Oct-2016  |
| FFS Due Date: <input type="text"/> | Negotiated Due Date: <input type="text"/> |
| OPP Target Date: <input type="text"/> | |
| Fast Track: <input type="checkbox"/> | New Ingredient: <input type="checkbox"/> |
| Receipt Description: AMENDMENT | |
| <input type="text"/> | |
| Form A: <input type="checkbox"/> | Signature Date: <input type="text"/> |
| Form B: <input type="checkbox"/> | Signature Date: <input type="text"/> |
| <div> <div>Receipt Content</div> <div>Paper Label</div> <div>Des</div> </div> <div>View/Edit</div> | |

New you
 Assigned
 10/25/16



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 20, 2016

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. JACOB. J. VUKICH
E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)
ATTN: MANAGER, US REGISTRATION, DUPONT CROP PROTECTION
CHESTNUT RUN PLAZA, 974 CENTRE ROAD, PO BOX 2915
WILMINGTON, DE 19805-

PRODUCT NAME: REFINED OIL OF NEPETA CATARIA 7% LIQUID
COMPANY NAME: E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)
OPP IDENTIFICATION NUMBER:
EPA FILE SYMBOL: 352-904
EPA RECEIPT DATE: 10/19/16

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 305-6928.

Sincerely,

A handwritten signature in black ink, appearing to be "S. J. Vukich".

Front End Processing Staff
Information Services Branch
Information Technology & Resources Management Division

8

Fee for Service {993712%~

This package includes the following

☐ New Registration

☒ Amendment

☐ Studies? ☐ Fee Waiver?

☐ volpay % Reduction: ____

for Division

☐ AD

☒ BPPD

☐ RD

Risk Mgr. 91

| | | |
|--------------------------|----|---|
| Receipt No. | S- | 993712 |
| EPA File Symbol/Reg. No. | | 352-904 |
| Pin-Punch Date: | | 10/19/2016 |

☒ This item is NOT subject to FFS action.

Action Code:

Requested:

Granted:

Amount Due: \$ _____

Parent/Child Decisions:

☒ Inert Cleared for Intended Use ☐ Uncleared Inert in Product

Reviewer: Andrew Bryce Date: 10/24/16

Remarks:

*Adding 2 to
Kod language*



DuPont Crop Protection
Stine-Haskell Research Center
P.O. Box 30
Newark, DE 19714-0030

October 17, 2016

DELIVERED BY COURIER SERVICE

Document Processing Desk (AMEND/NOTIF)
Menyon Adams PM
Office of Pesticide Programs (7504P)
U. S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

ACTION: Fast Track Amendment
FEE CATEGORY: Not Applicable **REGISTRATION FEE: Not Applicable**

E-mail contact: DuPont.USRegFee@USA.DuPont.com

SUBJECT: Notification of label change per PR Notice 2007-4 and Label Amendments for:

Refined Oil of *Nepeta cataria* (EPA Reg # 352-901)
Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg # 352-902)
Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg # 352-903)
Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg # 352-904)
Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg # 352-905)

Dear Ms Adams:

In accordance with PR Notice 2007-4, DuPont is notifying the Agency of revisions to the container handling statements for the above referenced products. This notification also represents the first registration action on these labels since the products were transferred from company # 71654 to company # 352 in May of 2014 and the labels have been reformatted to reflect registrant information for company # 352.

In addition to the above, the labels submitted herein also contain the following changes for consistency across the lotion and liquid products:

- The First Aid and Precautionary statements box has been relocated to its proper position on the label.
- Within the precautionary language on both lotion formulations (352-902 and 352-903), the phrase "Ask a doctor before using on children under 1 year of age" has been deleted. This phrase does not appear on the currently approved liquid formulation labels (352-904 and 352-905).
- An incorrect emergency contact number has been deleted and HOTLINE number information and the associated language has been added.
- On the lotion and liquid formulations (352-902, -903, -904, and -905), the word "treated" has been deleted from the following sentence in the Directions for Use: "Also wash ~~treated~~ clothing before wearing it again." This deletion was made because none of the labels recommend treatment of clothing.
- On the lotion formulations (352-902 and 352-903), the following statement has been deleted from the directions for use "An adult must apply this product to children under ten years of age". This phrase does not appear on the currently approved liquid formulation labels (352-904 and 352-905).

October 17, 2016

Page 2

- Additional optional marketing language has been added to the end of the label (please reference highlighted labels included).

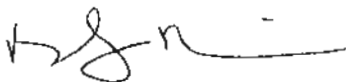
Attached please find the following documents supporting this notification:

- Application for Pesticide Registration (EPA form 8570-1) for each product – dated October 17, 2016
- Two copies of each of the above referenced labels one with changes highlighted
- A data matrix that includes all four formulations and the technical product
- Form 8570-34 for each product.

This notification is consistent with the guidance in PR Notice 2007-4 and the requirements of EPA's regulations at 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156. No other changes have been made to the labeling (except as noted). I understand that it is a violation of 18 U.S.C. Sec. 1001 to willfully make any false statement to EPA. I further understand that if the amended label is not consistent with the requirements of 40 CFR §§ 156.10, 156.140, 156.144, 156.146, and 156.156, this product may be in violation of FIFRA and may be subject to enforcement action and penalties under sections 12 and 14 of FIFRA.

Please let me know if you have any questions or concerns. I can be reached by phone at 302-451-4525 or via email at bonnie.j.bieber@usa.dupont.com.

Regards,



Bonnie J. Bieber
Product Registration Specialist



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

| | |
|---|---|
| Applicant's/Registrant's Name, Address, and Telephone Number DuPont Crop Protection, 1090 Elkton Rd, Newark, Delaware 19714-0030, 302-451-4525 | EPA Registration Number/File Symbol 352-904 |
| Active Ingredient(s) and/or representative test compound(s) Refined Oil of Nepeta cataria | Date 10-17-16 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Residential Outdoor | Product Name Refined Oil of Nepeta Catoria 7% Liquid |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

| | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| | | |
|---------------|---------------------|--|
| Signature | Date 17-Oct-2016 | Typed or Printed Name and Title Bonnie J. Bieber, Registration Specialist |
|---------------|---------------------|--|



United States
Environmental Protection Agency
Washington, DC 20460

☐ Registration
☐ Amendment
☒ Other

OPP Identifier Number

Application for Pesticide - Section I

| | | |
|---|--|--|
| 1. Company/Product Number DuPont/ 352-904 | 2. EPA Product Manager Menyon Adams | 3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted |
| 4. Company/Product (Name) DuPont/ Refined Oil of Nepeta cataria 7% Liquid | PM# | |
| 5. Name and Address of Applicant (Include ZIP Code) E. I. du Pont de Nemours & Company DuPont Crop Protection, Stine Haskell Research Center 1090 Elkton Rd. (S300-431) Newark, DE 19711 Attention: B. Bieber (302-451-4525) bonnie.j.bieber@dupont.com | | 6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____ |
| <input type="checkbox"/> Check if this is a new address | | |

Section - II

| | |
|--|--|
| <input checked="" type="checkbox"/> Amendment - Explain below. | <input type="checkbox"/> Final printed labels in response to Agency letter dated _____ |
| <input type="checkbox"/> Resubmission in response to Agency letter dated _____ | <input type="checkbox"/> "Me Too" Application. |
| <input type="checkbox"/> Notification - Explain below. | <input type="checkbox"/> Other - Explain below. |

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

Application to amend the product registration to revise the container handling statements in the STORAGE AND DISPOSAL text box as per the requirements of Subpart H of 40 CFR §156 ("Container Labeling") and EPA Pesticide Registration Notice 2007-4, add marketing language and make other minor formatting changes for Refined Oil of Nepeta cataria 7% Liquid label identified as D - 1941 101316.

Section - III

| | | | | | |
|---|---|--|--------------------------------------|---|----------------------------------|
| 1. Material This Product Will Be Packaged In: | | | | 2. Type of Container | |
| Child-Resistant Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Unit Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | Water Soluble Packaging <input type="checkbox"/> Yes <input type="checkbox"/> No | | <input type="checkbox"/> Metal | <input type="checkbox"/> Plastic |
| * Certification must be submitted | | | | <input type="checkbox"/> Glass | <input type="checkbox"/> Paper |
| | If "Yes" Unit Packaging wgt. | No. per container | If "Yes" Package wgt. | No. per container | Other (Specify) _____ |
| 3. Location of Net Contents Information <input type="checkbox"/> Label <input type="checkbox"/> Container | | 4. Size(s) Retail Container | | 5. Location of Label Directions <input type="checkbox"/> On Label <input type="checkbox"/> On Labeling accompanying product | |
| 6. Manner in Which Label is Affixed to Product <input type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled | | | <input type="checkbox"/> Other _____ | | |

Section - IV

| | | |
|--|-------------------------------------|---|
| 1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.) | | |
| Name Bonnie J Bieber | Title Registration Specialist | Telephone No. (Include Area Code) 302-451-4626 |
| Certification I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law. | | 6. Date Application Received (Stamped) |
| 2. Signature | 3. Title Registration Specialist | |
| 4. Typed Name Bonnie J. Bieber | 5. Date 17-October-2016 | |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 07, 2014

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MR. JACOB J. VUKICH
E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)
MANAGER, REGISTRATION & REGULATORY AFFAIRS
1007 MARKET STREET
WILMINGTON, DE 19898-0001

Dear Mr. Vukich:

Subject: Transfer of Pesticide Registrations and Data From Company Number 71654
to Company Number 352

Pursuant to your request in your letter and transfer agreement of December 13, 2013, and subsequently received information, we have approved the transfer of the following registrations from **E.I. DUPONT DE NEMOURS AND COMPANY (DUPONT CHEMICALS & FLUROPRODUCTS)**, company number **71654** to **E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)**, company number **352**.

The effective date of these changes is the date of this letter.

| <u>Registered Products</u> | <u>Old EPA Reg. No.</u> | <u>New EPA Reg. No.</u> |
|--|-----------------------------|-----------------------------|
| REFINED OIL OF NEPETA CATARIA | 71654-20 | 352-901 |
| REFINED OIL OF NEPETA CATARIA 7% LOTION | 71654-21 | 352-902 |
| REFINED OIL OF NEPETA CATARIA 15% LOTION | 71654-23 | 352-903 |
| REFINED OIL OF NEPETA CATARIA 7% LIQUID | 71654-24 | 352-904 |
| REFINED OIL OF NEPATA CATARIA 15% LIQUID | 71654-25 | 352-905 |

You should indicate the new company designation, new EPA Registration Number and new Establishment Number (if it has changed) on the labeling at the next printing which should occur no later than 18 months after the effective date of this transfer. After 18 months, any product released for shipment must bear the new Registration Number and Establishment Number. If you intend to use the labels which currently appear on the transferor's product after the effective date of the transfer, but within the 18 month grace period, you must maintain

complete and accurate records which identify by batch number, lot number, or other suitable description the quantities of such product bearing the transferor's label. Each container or package bearing the transferor's label which is released after the effective date of product registration transfer, must be clearly and accurately marked with the batch number, lot number or other descriptive designation used to identify the product in your records.

Supplemental distribution agreements of registered products do not transfer with the Section 3 registration. It is your responsibility as the registrant to notify any and all supplemental distributors of the transferred product(s) of this transfer agreement. If you wish to enter into supplemental distribution agreements of your product(s) under this new registration, the form "Notice of Supplemental Distribution of a Registered Pesticide Product," EPA Form 8570-5, must be submitted to the Agency for each supplemental distributorship.

You are required to contact your local EPA Regional Office to determine what effect this transfer of pesticide registrations has on the pesticide production establishment registration.

It will not be necessary to submit labeling for review if the only changes are in the company designation and the EPA Registration Number. Other changes in the product and/or labeling may require EPA review and approval prior to distribution or sale of the product containing the new registration number. In any correspondence on these products always refer to the U.S. EPA Registration Number listed above.

The transferred registration will have the same status under the Federal Insecticide, Fungicide and Rodenticide Act, as amended, 7 USC 136 et seq., as it had prior to the approval of this transfer.

When registrations are transferred from one company to a second company, all restrictions, data requirements, conditions (suspensions), and deadlines existing on the registrations are transferred with the registrations. The new company is responsible for adhering to or complying with all such restrictions, etc. on the acquired products.

With regard to deadlines, the transferee company is responsible for submitting all required data according to the schedules already established for the acquired products. Failure to do so will result in the issuance of a Notice of Intent to Suspend. Requests from transferee companies for additional time to submit, because they acquired the registration(s) after the 3(c)(2)(B) request was issued will not be granted. If a transferee company has other valid reasons for delays in the testing which were clearly outside of their control, then such requests for time extensions will be considered in accordance with the established procedures. Transfers occurring while a 3(c)(2)(B) request is being issued or during the 90-day response time are subject to the same conditions expressed above.

Registration is in no way to be construed as an endorsement or approval of these products by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with FIFRA.

Furthermore, the transfer of the subject registrations is approved under the condition that the annual maintenance fee obligation has been fully satisfied. The annual maintenance fee

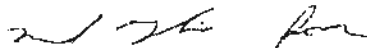
is based solely on the total number of active section 3 and section 24(c) registrations held by the transferor. If the annual maintenance fee has not been fully satisfied, the transferee and transferor will be notified to comply within a specified time period or the affected registrations may be canceled.

The Agency acknowledges it has received a request for data transfer dated December 13, 2013, with subsequently received information, to transfer data ownership from the transferor to the transferee. The data transfer is effective the date of this letter. After this date **E. I. DU PONT DE NEMOURS AND COMPANY (S300/419)** will be considered the data owner. This action will not automatically reflect on the Data Submitters List. If you want to be added to the Data Submitters List, you must submit a request to:

Document Processing Desk (DSL)
Office of Pesticide Programs (7504P)
U.S. Environmental Protection Agency
Ariel Rios Building
1200 Pennsylvania Avenue, NW
Washington, DC 20460

By copy of this letter we are informing the transferor of these changes. If you have any questions about this transfer approval please contact Louis Vaughn at (703) 308-8114.

Sincerely,



Steve Robbins, Chief
Information Services Branch
Information Technology & Resource Management Div. (7504P)

cc: MR.THOMAS C. MCENTEE
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICALS & FLUOROPRODUCTS
P.O. Box 80402
WILMINGTON, DE 19880-0402

RE: L_71654_RAD_352_05_07_2014

APPENDIX A

Reference: 40 CFR § 152.98 (a) (3)

For Exclusive Use See: 7 USC § 136 et seq., (FIFRA) Sec. 3 (c) (1) (F) and 40 CFR § 152.83(c)

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|--|--|-------------------------------------|------------------------------------|--|
| 46977300 | Submission of Product Chemistry and Toxicity Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 15% Lotion. Transmittal of 8 Studies | E. I. DU PONT DE NEMOURS AND COMPANY | 11/1/2006 | Y | 11/1/2016 |
| 46977301 | Lotion 1630802C: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure. Project Number: 834, 16615, DUPONT/20904. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977302 | Lotion 1630802C: Acute Dermal Toxicity Study in Rats. Project Number: DUPONT/20889, 16615, 673. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977303 | Lotion 1630802C: Acute Eye Irritation Study in Rabbits. Project Number: DUPONT/20905, 16615, 602. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977304 | Lotion 1630802C: Acute Dermal Irritation Study in Rabbits. Project Number: DUPONT/20707, 16615, 1008. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977305 | Lotion 1630802C: Local Lymph Node Assay (LLNA) in Mice. Project Number: DUPONT/20161, 16615, 1234. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977306 | Formulation CU 1630802C: Median Lethal Inhalation Concentration Waiver Request. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977310 | Summary of Physical and Chemical Characteristics of Formulations CU 1630802C and CU 1630802D. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|---|--|-------------------------------------|------------------------------------|--|
| 46977311 | Physical and Chemical Characteristics of 15 wt.% Hydrogenated Catmint Oil Lotion: Physical State, Flammability and pH. Project Number: 3280/14. | E. I. DU PONT DE NEMOURS AND COMPANY | 11/1/2006 | Y | 11/1/2016 |
| 46977400 | Submission of Product Chemistry, Toxicity, and Efficacy Data in Support of the Application for Registration of Refined Oil Of Nepeta cataria. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977401 | Hydrogenated Catmint Oil: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure. Project Number: DUPONT/17740, 15926, 834. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977402 | Hydrogenated Catmint Oil: Acute Dermal Toxicity Study in Rats. Project Number: DUPONT/17550, 15926, 673. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977403 | Hydrogenated Catmint Oil: Acute Eye Irritation Study in Rabbits. Project Number: DUPONT/17533, 15926, 602 | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977404 | Hydrogenated Catmint Oil: Acute Dermal Irritation Study in Rabbits. Project Number: DUPONT/17519, 15926, 1008. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977405 | Hydrogenated Catmint Oil: Local Lymph Node Assay (LLNA) in Mice. Project Number: DUPONT/17409, 15926, 1234. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977406 | Hydrogenated Catmint Oil: Inhalation Median Lethal Concentration (LC50) Study in Rats. Project Number: DUPONT/17408, 15926, 721. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|---|--|-------------------------------------|------------------------------------|--|
| 46977407 | Hydrogenated Catmint Oil: Subchronic Toxicity 90-Day Oral Gavage Study and Immunotoxicity 28-Day Oral Gavage Study in Rats. Project Number: DUPONT/17324, 15926, 1026 | E. I. DU PONT DE NEMOURS AND COMPANY | 11/1/2006 | Y | 11/1/2016 |
| 46977408 | Hydrogenated Catmint Oil: Developmental Toxicity Study in Rats. Project Number: DUPONT/17343, 15926, 841. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977409 | Hydrogenated Catmint Oil: Acute Oral Neurotoxicity Study in Rats. Project Number: DUPONT/19148, 15926, 1261. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977410 | Hydrogenated Catmint Oil: Bacterial Reverse Mutation Test. Project Number: DUPONT/17471, 15926, 500. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977411 | Hydrogenated Catmint Oil: In Vitro Mammalian Chromosome Aberration Study in Human Peripheral Blood Lymphocytes: Final Report. Project Number: AB15GY/341/BTL, H/26993, 15926. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977412 | Hydrogenated Catmint Oil: Mouse Bone Marrow Micronucleus Test. Project Number: DUPONT/18623, 15926, 572. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977413 | Hydrogenated Catmint Oil: In Vitro Mammalian Cell Gene Mutation Test (L5178Y/TK+/- Mouse Lymphoma Assay). Project Number: AB15GY/704/BTL, 15926, 1537. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977415 | Hydrogenated Catmint Oil: 28-Day Repeated-Dose Dermal Toxicity Study in Rats. Project Number: DUPONT/17327, 15926, 1012 | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|--|--|-------------------------------------|------------------------------------|--|
| 46977420 | Physical and Chemical Characteristics of Hydrogenated Catnip Oil (HCO) Color, Physical State, Odor, Flammability, pH and Viscosity: Final Report. Project Number: 3280/17. | E. I. DU PONT DE NEMOURS AND COMPANY | 11/1/2006 | Y | 11/1/2016 |
| 46977422 | Summary of Physical and Chemical Characteristics of Technical Grade Active Ingredient: (Refined Oil of Nepeta cataria). | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977424 | Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine. Project Number: G3130306001A044, 0306/313/0142. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 46977425 | Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida. Project Number: G3130306001A044, 0306/313/0143. | E. I. DU PONT DE NEMOURS AND COMPANY, | 11/1/2006 | Y | 11/1/2016 |
| 47003100 | Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria. | E. I. DU PONT DE NEMOURS AND COMPANY, | 112/8/2006 | Y | 12/8/2016 |
| 47003101 | Product Identity and Composition (Refined Oil of Nepeta cataria) | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/8/2006 | Y | 12/8/2016 |
| 47003102 | Solubility Analysis, and Storage Stability Analysis of Hydrogenated Catnip Oil (HCO) Active Ingredient project Number: P00010, P0002395. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/8/2006 | Y | 12/8/2016 |
| 47003103 | Enforcement Analytical Method for the Active Ingredient: (Hydrogenated Catnip Oil). Project Number: DUPONT/P00010, P0002366. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/8/2006 | Y | 12/8/2016 |

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|---|--|-------------------------------------|------------------------------------|--|
| 47003104 | Certified Limits and Supplement to Preliminary Analysis. | E. I. DU PONT DE NEMOURS AND COMPANY | 12/8/2006 | Y | 12/8/2016 |
| 47003105 | Determination of Boiling Point and Vapor Pressure (Static Method) for a Liquid TGA1 and Viscosity for Two Lotion Formulations. Project Number: DUPONT/P00011, 50487. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/8/2006 | Y | 12/8/2016 |
| 47003300 | Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 15% Lotion. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/8/2006 | Y | 12/8/2016 |
| 47003301 | Identity and Composition of Formulations CU 1630802C and CU 1630802D. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/8/2006 | Y | 12/8/2016 |
| 47003302 | Analytical Method for Formulations: Refined Oil of Nepeta cataria 15% Lotion. Project Number: 00010, 0002366, E108324/119. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/8/2006 | Y | 12/8/2016 |
| 47003303 | Certified Limits Lotion Formulation CLI 1630802C and CLI 1630802D. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/8/2006 | Y | 12/8/2016 |
| 47013900 | Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 7 Percent Lotion. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/27/2006 | Y | 12/27/2016 |
| 47013901 | Physical and Chemical Characteristics of 7 wt Percent Hydrogenated Catmint Oil Lotion: Physical State, Flammability and pH: Nepeta cataria Oils. Project Number: 3280/13. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/27/2006 | Y | 12/27/2016 |

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|---|--|-------------------------------------|------------------------------------|--|
| 47015600 | Submission of Toxicity and Efficacy Data in Support of the Application for Registration of Refined Oil of Nepeta cataria. | E. I. DU PONT DE NEMOURS AND COMPANY | 12/28/2006 | Y | 12/28/2016 |
| 47015601 | Hydrogenated Catmint Oil: In Vitro Kinetics in Rat and Human Skin. Project Number: 19930, 15926, 1377. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/28/2006 | Y | 12/28/2016 |
| 47015602 | Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine. Project Number: G3130306002A121, 0306/313/0141. | E. I. DU PONT DE NEMOURS AND COMPANY, | 12/28/2006 | Y | 12/28/2016 |
| 47113800 | Submission of Efficacy Data in Support of the Application for Registration of Refined Oil of Nepeta cataria Technical, Refined Oil of Nepeta cataria 15% Lotion, and Refined Oil of Nepeta cataria 7% Lotion. | E. I. DU PONT DE NEMOURS AND COMPANY, | 04/24/2007 | Y | 04/24/2017 |
| 47113801 | Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Black Flies in Maine. Project Number: 0306/313/0141. | E. I. DU PONT DE NEMOURS AND COMPANY, | 04/24/2007 | Y | 04/24/2017 |
| 47113802 | Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Maine. Project Number: 0306/313/0142, G3130306001A044. | E. I. DU PONT DE NEMOURS AND COMPANY, | 04/24/2007 | Y | 04/24/2017 |
| 47113803 | Documentation of Ethical Conduct: Evaluation of the Efficacy of Personal Repellents Against Mosquitoes in Florida. Project Number: 0306/313/0143, G3130306001A044. | E. I. DU PONT DE NEMOURS AND COMPANY, | 04/24/2007 | Y | 04/24/2017 |
| 47181300 | Submission of Toxicity, Product Chemistry and Efficacy Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 15% Liquid. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

NOV 26 2008

OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

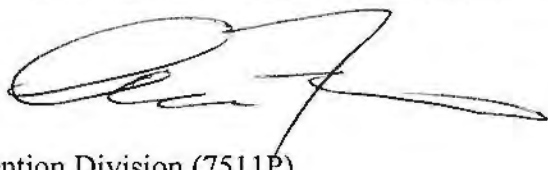
MEMORANDUM

DATE: 11/26/2008.

SUBJECT: Science Review in Support of the Registration.

Decision Number: 371862
 DP Number: 338694
 EPA File Symbol Number: 71654-EL and 71654-EU
 Chemical Class: Biochemical
 PC Code: 004801
 CAS Number: 8023-84-5
 Active Ingredient Tolerance Exemptions: No tolerance exemption. Non- food product.
 MRID Numbers:

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FROM: Clara Fuentes, Ph. D. Biologist 
 Biochemical Pesticides Branch
 Biopesticides & Pollution Prevention Division (7511P)

TO: Raderrio Wilkins, Regulatory Action Leader
 Biochemical Pesticides Branch
 Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

DuPont Chemical Solutions Enterprise is requesting registration of two liquid spray formulations, EPA Reg. No. **71654-EL**, and EPA Reg. No. **71654-EU**, containing different concentrations, 15 % and 7 % w/w of the new active ingredient, refined oil of *Nepeta cataria*, respectively. In support of registrations of EPA Reg. No. **71654-EL**, and EPA Reg. No. **71654-EU**, the registrant is requesting to bridge to acute mammalian toxicity generated on 15 % liquid spray formulation, EPA Reg. No. 71654-EL, to support registration of 7 % liquid spray formulation, EPA Reg. No. 71654-EU.

COMMENTS AND RECOMMENDATIONS

Acute mammalian toxicity (EPA Reg. No. 71654-EN (TGAI); 71654-ER and 71654-EG)

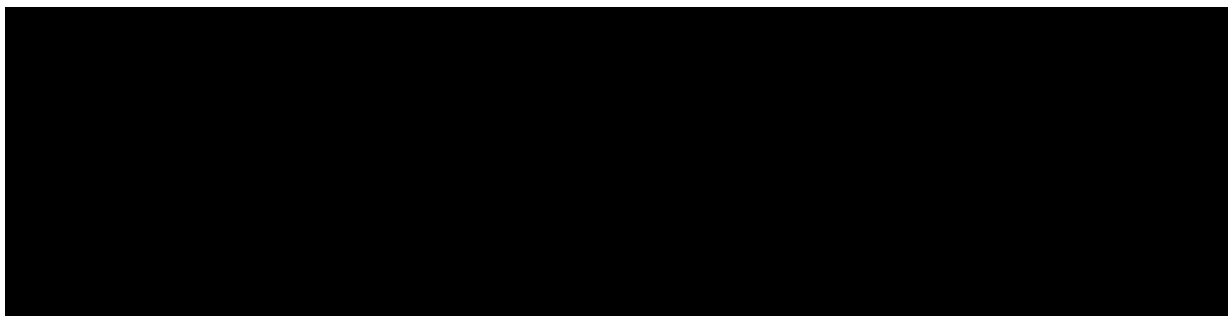
1. Acute mammalian toxicity submitted in support of registration of TGAI (EPA Reg. No. 71654-EN) and end-use lotion formulations, EPA Reg. No. 71654-EG and EPA Reg. No. 71654-ER, containing 7 % w/w and 15 % w/w new active ingredient, *Nepeta cataria*, respectively, are **acceptable** by Roger Gardner's review, dated 10/04/07. In addition, in MRID 47362604, the registrant addressed questions raised by the Agency concerning a positive mouse lymphoma assay in MRID 46977413. The discussion provides adequate rationale for the TGAI being non-mutagenic, and explores the concept of false test positives and weight of evidence decision for overall effect categorization (Dr. Kent R. Carlson, 08/12/2008).

Bridging product specific Tier I acute toxicity data

2. It is acceptable to bridge to the product specific acute toxicity data that was generated on the 15 % a.i. lotion formulation, 71654-EG, for supporting registration of 7 % a.i. lotion formulation, 71654-ER, because the 2 products are substantially similar in their composition. They contain the same inert ingredients only in slightly different concentrations; formulation 71654-ER (7% w/w a.i.) contains approximately half the concentration of the same active ingredient contained in 71654-EG.
3. Since the lotions formulations are substantially similar, it is acceptable to bridge to toxicity data generated on the 15 % a.i. liquid spray formulation to support registration of the 7 % a.i. liquid spray formulation.

CSF for EPA Reg. No. 71654-ER and 71654-EG

4. The CSF deficiencies identified for lotion formulations, 7 % (71654-EG) and 15 % (71654-ER) in the Agency letter dated 10/16/2008, have not been addressed, and they need to be resolved. The registrant needs to address the Agency recommendation (EPA letter dated 10/16/2008) to contact Inert Ingredients Branch (IIAB) for the following inert ingredients:



Product performance data requirement for EPA Reg. No. 71654-EL and 71654-EU

7. The registrant has adequately addressed in MRID 47362-03, technical and ethical deficiencies identified in original efficacy studies.
8. The registrant explains that the dose rates reported in Table 1 below correspond to 1,792 mg/m² and 3,780 mg/ m² of active ingredient in 7 % and 15 % lotions, respectively; and 1,116 mg/m² and 2,412 mg/m² of active ingredient in liquid spray formulations, respectively.

Reported amounts of applied test materials are as follows in Table 1.

| Table 1. Application of Test Material to Subjects | | | | |
|--|-----------|-----------|------------|------------|
| Units | 7% Lotion | 7% Liquid | 15% Lotion | 15% Liquid |
| mg/cm ² | 2.56 | 1.60 | 2.52 | 1.61 |
| g/600cm ² | 1.536 | 0.960 | 1.512 | 0.966 |
| mg/m ² | 1792 | 1116 | 3780 | 2412 |
| OPPTS 810.3700 rec. values (g/600cm ²) | 1.50 | 1.0 | 1.50 | 1.0 |

Protocol Amendments:

The registrant also explains that the protocol was amended to include evaluation of the 7 % w/w a.i. formulations. The original protocol only included testing on the 15 % w/w a.i. formulations.

9. MRID 47362-03 shows that the insect by formulation interaction is highly significant for mosquitoes specially, at lower concentrations of active ingredient. Repellency against black flies was not significantly affected by the interaction between type of formulation and active ingredient concentration. Table 2.

| Table 2. ANOVA Addressing Active Ingredient Concentration and Formulation Type Effects | | | |
|---|---------------------------------|----------------------|----------------------|
| Insect | Source of Variation | % of Total Variation | P value |
| Mosquito | Interaction | 6.13 | 0.0251* |
| Mosquito | Formulation | 21.43 | <0.0001*** |
| Mosquito | Active Ingredient Concentration | 12.86 | 0.0015** |
| Blackfly | Interaction | 2.12 | 0.2455 ^{ns} |
| Blackfly | Formulation | 2.41 | 0.2159 ^{ns} |
| Blackfly | Active Ingredient Concentration | 10.56 | 0.0112* |
| *** = extremely significant, ** = very significant, * = significant, ns = not significant | | | |

10. Product specific performance data shows the following protection times for each formulation on 2 different target pests, mosquitoes and black flies, tested in the field.

Descriptive statistics (GraphPad Prism v.4) were used in order to describe field test results (complete protection time in minutes). Mean complete protection times against mosquitoes averaged 4 hours 17 minutes (7% liquid), >6 hours 43 minutes (7% lotion), 6 hours 25 minutes (15% liquid), and >7 hours 7 minutes (15% lotion). Mean complete protection times against blackflies averaged >5 hours 59 minutes (7% liquid), >6 hours 59 minutes (7% lotion), > 7 hours 32 minutes (15% liquid), and >7 hours 34 minutes (15% lotion) (p15). The descriptive statistics are presented in Table 3 and 4.

Table 3. Complete Protection Time for the 7% Formulations as Assessed by Descriptive Statistics

| | 7% Lotion | | | | 7% Liquid | | | |
|--|-------------|-------------|--------------|--------------|-------------|-------------|--------------|--------------|
| | FL-mosquito | ME-mosquito | ME-black fly | ME-black fly | FL-mosquito | ME-mosquito | ME-black fly | ME-black fly |
| N | 5 | 5 | 5 | 5 | 5 | 5 | 5 | 5 |
| Minimum | 270 | 410 | 338 | 139 | 192 | 27 | 327 | 121 |
| 25%ile | 276 | 413 | 344 | 310 | 221 | 151 | 347 | 146 |
| Median | 282 | 480 | 480 | 480 | 252 | 288 | 476 | 213 |
| 75%ile | 469 | 480 | 480 | 480 | 297 | 347 | 480 | 480 |
| Maximum | 480 | 480 | 480 | 480 | 324 | 347 | 480 | 480 |
| Mean | 354 | 453 | 425 | 412 | 257 | 257 | 426 | 293 |
| StdDev | 105 | 37 | 75 | 152 | 47 | 132 | 74 | 174 |
| Std Error | 47 | 17 | 33 | 68 | 21 | 59 | 33 | 78 |
| Lower 95% CI | 224 | 407 | 332 | 222 | 199 | 92 | 335 | 77 |
| Upper 95% CI | 485 | 499 | 518 | 601 | 316 | 421 | 517 | 509 |
| Normality P value | >0.10 | >0.10 | >0.10 | >0.10 | >0.10 | >0.10 | >0.10 | >0.10 |
| Passed normality test? ($\alpha=0.05$) | yes | yes | yes | yes | yes | yes | yes | yes |
| Skewness | 0.30 | -0.30 | -0.30 | -1.1 | 0.032 | -0.91 | -0.37 | 0.22 |
| Kurtosis | -2.2 | -2.2 | -2.2 | -0.92 | -1.5 | -1.1 | -2.1 | -2.2 |

Table 4. Complete Protection Time for the 15% Formulations as Assessed by Descriptive Statistics

| | 15% Lotion | | | | 15% Liquid | | | |
|--|-------------|-------------|--------------|--------------|-------------|-------------|--------------|--------------|
| | FL-mosquito | ME-mosquito | ME-black fly | ME-black fly | FL-mosquito | ME-mosquito | ME-black fly | ME-black fly |
| N | 10 | 10 | 10 | 10 | 10 | 10 | 10 | 10 |
| Minimum | 309 | 480 | 318 | 335 | 281 | 306 | 360 | 177 |
| 25%ile | 320 | 480 | 418 | 458 | 295 | 451 | 444 | 448 |
| Median | 341 | 480 | 476 | 480 | 307 | 480 | 480 | 480 |
| 75%ile | 461 | 480 | 480 | 480 | 331 | 480 | 480 | 480 |
| Maximum | 480 | 480 | 480 | 480 | 362 | 480 | 480 | 480 |
| Mean | 374 | 480 | 447 | 461 | 314 | 457 | 461 | 443 |
| StdDev | 68 | 0.0 | 52 | 46 | 24 | 56 | 38 | 95 |
| Std Error | 22 | 0.0 | 17 | 15 | 7.5 | 18 | 12 | 30 |
| Lower 95% CI | 325 | 480 | 409 | 428 | 297 | 417 | 433 | 375 |
| Upper 95% CI | 422 | 480 | 484 | 494 | 331 | 497 | 488 | 511 |
| Normality P value | >0.10 | - | >0.10 | 0.03 | >0.10 | 0.0287 | 0.09 | >0.10 |
| Passed normality test? ($\alpha=0.05$) | yes | - | yes | no | yes | no | yes | yes |

Table 4. Complete Protection Time for the 15% Formulations as Assessed by Descriptive Statistics

| | | | | | | | | |
|----------|------|-----|------|------|-------|------|------|------|
| Skewness | 0.61 | 0.0 | -1.4 | -2.0 | 0.54 | -1.9 | -1.7 | -2.2 |
| Kurtosis | -1.5 | 0.0 | 0.77 | 2.4 | -0.78 | 2.3 | 1.8 | 3.2 |

The lotion formulations outperformed the liquid formulations with equivalent concentrations of a.i. This main formulation effect is more apparent at lower concentrations of a.i. (7 %).

11. The Agency identified ethical issues of concern regarding the conduct of the efficacy studies. These issues include use of employees of Insect Control and Research laboratory as test subjects, lack of test site monitoring immediately prior to field testing, and lack of risk minimization measures in the study design; i.e., use of bites instead of landings to estimate protection time against mosquitoes. These issues have been adequately addressed by the registrant in MRID 473626-03.
12. The registrant has provided the following information regarding the potential for mosquito and blackfly-borne diseases. These factors illustrate the low probability for contracting mosquito or black fly-borne diseases and that if such occurred, the workers would be covered medically. The rationales for maintaining human safety in this study were as follows:
 - 1) Each subject gave Informed Consent.
 - 2) Each subject was covered in entirety from biting insects, except for the open testing skin patches.
 - 3) Black fly tests were considered completed after landings, not bitings.
 - 4) Mosquito tests were considered completed after 2 mosquito bites within 30 minutes of each other (so the potential total number of bites per day was marginal).
 - 5) Exposure protocols were cleared through DuPont's Human Studies Review Board and an external Institutional Review Board.
 - 6) Each subject's shoes were treated with Permanone® to discourage tick attachment while in the field.
 - 7) There had been no reported cases of West Nile Virus (WNV) in Maine as of the date of testing.
 - 8) *Culex* spp. mosquitoes (WNV carriers) are uncommon in Maine near the study sites.
 - 9) *Ochlerotatus intrudens* was the only positively identified mosquito in the Maine field trial. This mosquito has not been identified as a WNV carrier by the CDC.
 - 10) *Culex* spp. mosquitoes are uncommon at the Florida site.
 - 11) Potential WNV carrier species including *Psorophora ferox*, *Ochlerotatus atlanticus/tormentor*, *Ochlerotatus taeniorhynchus*, and *Culiseta melanura* were present throughout the FL tests.
 - 12) The potential WNV carrier *Culex ioambdis* was present only late in the study, so probably contributed little to the bite pressure.
 - 13) The subjects were employees of Insect Control & Research and so were covered by Workman's Compensation if medical problems occurred.

15. As stated in the registrant's response to deficiencies, ("Potential WNV carrier species including *Psorophora ferox*, *Ochlerotatus atlanticus/tormentor*, *Ochlerotatus taeniorhynchus*, and *Culiseta melanura* were present throughout the FL tests.") the risk for WNV transmission exists, and it could have been reduced further through the inclusion of risk minimization measures in the study design.

Non-target data for new end-use products

16. Risk of exposure to non-target organisms is not expected from the use of these products as insect repellents. The registrant has adequately addressed Tier I non-target toxicity requirement applicable to TGAI by providing rationale for supporting data waiver request from the requirement of non-target organisms' studies in a letter dated Nov. 24, 2008.

liquid 15% MRIDs TOX

471813-01 - Oral 5,000 mg/kg

" -02 - Dermal tox " " "

" -03 - Eye II eye irritant

-04 - Dermal init. (no irritant) IV

06 - Inhalation IV

hypersensitivity -

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|--|--|-------------------------------------|------------------------------------|--|
| 47181301 | H-27923: Acute Oral Toxicity Study in Rats - Up-and-Down Procedure. Project Number: DUPONT/22811, 17035, 834. | E. I. DU PONT DE NEMOURS AND COMPANY | 07/18/2007 | Y | 07/18/2017 |
| 47181302 | H-27923: Acute Dermal Toxicity Study in Rats. Project Number: DUPONT/22750, 17035, 673. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181303 | H-27923: Acute Eye Irritation Study in Rabbits. Project Number: DUPONT/22812, 17035, 602. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181304 | H-27923: Acute Dermal Irritation Study in Rabbits. Project Number: DUPONT/22470, 17035, 1008. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181305 | H-27923: Local Lymph Node Assay (LLNA) in Mice. Project Number: DUPONT/21296, 17035, 1234. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181306 | H-27923: Inhalation Median Lethal Concentration (LC50) Study in Rats. Project Number: DUPONT/21690, 17035, 721. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181307 | Identity and Composition of 15% Refined Oil of Nepeta cataria Liquid Formulation. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181308 | Physical and Chemical Characteristics of Refined Oil of Nepeta cataria 15% (w/w) Liquid Formulation 16307048: Physical State, Flammability, pH, Viscosity and Relative Density. Project Number: 3280/33, APEX838/06. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|--|--|-------------------------------------|------------------------------------|--|
| 47181309 | Certified Limits: 1630704A Liquid and 1630704B Liquid. | E. I. DU PONT DE NEMOURS AND COMPANY | 07/18/2007 | Y | 07/18/2017 |
| 47181310 | Summary of Physical and Chemical Characteristics of Formulations CU 1630704A and CU 1630704A | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181311 | Supplement to Efficacy Studies Submitted Under Refined Oil of Nepeta cataria Technical and Manufacturing-Use Product: EPA File Symbol 71664-ER: 1630704A Liquid and 1630704B Liquid | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181400 | Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 7% Liquid. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181401 | Identity and Composition of 7% Refined Oil of Nepeta cataria Liquid Formulation. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47181402 | Physical and Chemical Characteristics of Refined Oil of Nepeta cataria 7% (w/w) Liquid Formulation 1630704A: Physical State, Flammability, pH, Viscosity, Relative Density. Project Number: 3280/32. | E. I. DU PONT DE NEMOURS AND COMPANY, | 07/18/2007 | Y | 07/18/2017 |
| 47234300 | Submission of Product Chemistry Data in Support of the Application for Registration of Refined Oil of Nepeta cataria 15% Lotion. | E. I. DU PONT DE NEMOURS AND COMPANY, | 01/05/2007 | Y | 01/05/2017 |
| 47234301 | Characterization of Aged Hydrogenated Catnip Oil (HCO) Formulations. Project Number P0002216, P00009. | E. I. DU PONT DE NEMOURS AND COMPANY, | 01/05/2007 | Y | 01/05/2017 |

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|---|--|-------------------------------------|------------------------------------|--|
| 47362600 | Submission of Product Chemistry, Toxicity and Efficacy Data in Support of the Application for Registration of the Refined Oil of <i>Nepeta cataria</i> . | E. I. DU PONT DE NEMOURS AND COMPANY | 03/04/2008 | Y | 03/04/2018 |
| 47362602 | Supplement: Prediction of Minor Constituents of Refined Oil of <i>Nepeta cataria</i> as Likely Hydrogenation Products. | E. I. DU PONT DE NEMOURS AND COMPANY, | 03/04/2008 | Y | 03/04/2018 |
| 47362603 | Supplement to 'Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Maine' (MRID 46977424), 'Evaluation of the Efficacy of Personal Repellents against Mosquitoes in Florida' (MRID 46977425) and 'Evaluation of the Efficacy of Personal Repellents against Blackflies in Maine' (MRID 47015602). | E. I. DU PONT DE NEMOURS AND COMPANY, | 03/04/2008 | Y | 03/04/2018 |
| 47362604 | Response from DuPont to the U.S. EPA Genetic Toxicity Recommendation in 'Science Review and Human Health Risk Assessment in Support of the Registration of the Insect Repellent Refined Oil of <i>Nepeta cataria</i> (TGA), and Two Lotion End-Use Products'. | E. I. DU PONT DE NEMOURS AND COMPANY, | 03/04/2008 | Y | 03/04/2018 |
| 47370400 | Submission of Product Chemistry Data in Support of the Application for Registration of <i>Nepeta cataria</i> oils. | E. I. DU PONT DE NEMOURS AND COMPANY, | 03/13/2008 | Y | 03/13/2018 |
| 47370401 | Supplement to Preliminary Analysis: Physical and Chemical Characteristics: (<i>Nepeta cataria</i> oils). | E. I. DU PONT DE NEMOURS AND COMPANY, | 03/13/2008 | Y | 03/13/2018 |
| 47422900 | Submission of Product Chemistry Data in Support of the Applications for Registration of Refined Oil of <i>Nepeta cataria</i> 15% Lotion and Refined Oil of <i>Nepeta cataria</i> 7% Lotion. | E. I. DU PONT DE NEMOURS AND COMPANY, | 05/13/2008 | Y | 05/13/2018 |
| 47422901 | Supplement to Product Chemistry Requirements: (Refined Oil of <i>Nepeta cataria</i>). | E. I. DU PONT DE NEMOURS AND COMPANY, | 05/13/2008 | Y | 05/13/2018 |

| MRID or other Identifying Administrative Number | Name of the Study | Name of Person or Lab that Conducted the Study | Date the Study was Submitted to EPA | Is Exclusive Use Claimed? (Y or N) | If Yes then, Date Period of Exclusive Use Ends |
|---|---|--|-------------------------------------|------------------------------------|--|
| 47425400 | Submission of Product Chemistry Data in Support of the Applications for Registration of Refined Oil of Nepeta cataria 15% Liquid and Refined Oil of Nepeta cataria 7% Liquid. | E. I. DU PONT DE NEMOURS AND COMPANY | 05/15/2008 | Y | 05/15/2018 |
| 47425401 | Identity and Composition of 1630704A Liquid and 1630704B Liquid. | E. I. DU PONT DE NEMOURS AND COMPANY, | 05/15/2008 | Y | 05/15/2018 |
| 48106200 | Submission of Product Chemistry Data in Support of the Registrations of Refined Oil of Nepeta cataria Technical, Refined Oil of Nepeta cataria 15% Lotion, Refined Oil of Nepeta cataria 7% Lotion, Refined Oil of Nepeta cataria 15% Liquid and Refined Oil of Nepeta cataria 7% Liquid. | E. I. DU PONT DE NEMOURS AND COMPANY, | 05/27/2008 | Y | 05/27/2018 |
| 48106201 | One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. | E. I. DU PONT DE NEMOURS AND COMPANY, | 05/27/2008 | Y | 05/27/2018 |

MATERIAL TO BE ADDED TO JACKET

REG #: 11654-24

Description: Refined Oil of Mepha Cathin
7% Liquid

| | | |
|---|---|-------------|
| if applicable, check all that are attached: | | Send to CSC |
| <input type="checkbox"/> | new stamped accepted label | |
| <input type="checkbox"/> | new CSF | |
| <input type="checkbox"/> | notification | |
| <input checked="" type="checkbox"/> | other: <u>Unacceptable Storage Stability</u> <u>Corrosion Characteristic Study</u> | |

Instructions:

Attach this sheet to the top of **ALL** material sent to the file room (both loose paper and new material in jackets). This sheet will be imaged; a clear description will aid in finding the material in the e-jacket. Remove staples from all material. If returning loose paper then hold together with a binder or paper clip. CSFs should be placed in the CSF folder (if returning jacket) or covered with a red CBI sheet (if returning loose paper). Material to be returned to file room should be placed in the appropriate bin.

Reviewer: Menyon Adams Date: 09/01/10

Phone: (703) 347-8496 Division: BPPD

Receipt for Section 3

S: 875469

Resubmission: ☐ Yes ☒ No

Regulatory Type: Product Registration - Section 3

Fee For Service: ☐ Yes ☒ No

Application Type: Miscellaneous Receipt

Billable: ☒ Yes ☐ No


Company: 71654 E.I. DUPONT DE NEMOURS AND COMPANY V


Risk Manager: Biologicals & Pollution Prevention Division, PM Team 91


Product #: 71654-24 Product Name: REFINED OIL OF NEPETA CATARIA 7% LIQUID


Override#:

Me Too Section3: Me Too Product Name:

Application Date: 21-May-2010 

OPP Rec'd Date: 27-May-2010 

Front End Date: 27-May-2010 

Risk Manager Send Date: 27-May-2010 

FFS Due Date:

Negotiated Due Date:

OPP Target Date:

Fast Track: ☐

New Ingredient: ☐

Receipt Description:

1 yr. storage stability and corrosion characteristics

New Ingredient Request Date:

New Ingredient Received Date:

Form A: ☐ Signature Date:

Form B: ☐ Signature Date:

Print Letter

Enter More Information

Tracking

Receipt Content

Des

Study

View/Edit



DuPont Chemicals and Fluoroproducts

May 21, 2010

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Refined Oil of *Nepeta cataria* technical; EPA Reg. No. 71654-20
Refined Oil of *Nepeta cataria* 15% Lotion; EPA Reg. No. 71654-23
Refined Oil of *Nepeta cataria* 7% Lotion; EPA Reg. No. 71654-21
Refined Oil of *Nepeta cataria* 15% Liquid; EPA Reg. No. 71654-25
Refined Oil of *Nepeta cataria* 7% Liquid; EPA Reg. No. 71654-24

Reference: OPPTS 830.6317 (Storage Stability)

Dear Ms. Hollis,

Please refer to the attached study, which was listed as a condition of issuance of the subject registrations.

Should there be any questions, please feel free to call or e-mail.. Thank you for your assistance with our applications.

Sincerely,

A handwritten signature in cursive script, appearing to read "Thomas C. McEntee".

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(978) 312-1160
(302) 695-6856



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

DATE: August 25, 2010

SUBJECT: Science Review of Storage Stability and Corrosion Characteristics Studies for Several Products Containing Oil of *Nepeta Cataria* as their Active Ingredient: Refined Oil of *Nepeta cataria* Technical; Refined Oil of *Nepeta cataria* 7% Lotion; Refined Oil of *Nepeta cataria* 15% Lotion; Refined Oil of *Nepeta cataria* 7% Liquid; Refined Oil of *Nepeta cataria* 15% Liquid

EPA File Symbol Numbers: 71654-20; 71654-21; 71654-23; 71654-24; 71654-25
Decision Numbers: 434656; 434657; 434659; 434660; 434661
DP Barcode: 378691; 378694; 378693; 378696; 378695
PC Code: 004801
CAS Number: 8023-84-5
MRID Number: 48106201

FROM: Gina M. Casciano, M.S., Biologist /s/ 8/25/2010
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH: Russell S. Jones, Ph.D., Senior Biologist /s/ 8/25/2010
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Menyon Adams, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

ACTION REQUESTED

E. I. du Pont de Nemours and Company requests the review of a recently completed Storage Stability and Corrosion Characteristics study that includes five products containing *Nepeta cataria* oils as their active ingredient (MRID 48106201). Each product was granted a Conditional Section 3(c) Registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) between December 4, 2008, and March 26, 2009.

RECOMMENDATIONS AND CONCLUSIONS

1. Storage stability data presented appear to indicate that the test substance was stable for 1 year with minimum change in active ingredient concentration and no change in appearance. However, the registrant did not clearly demonstrate that the two active ingredients present in their technical grade active ingredient (TGAI) are stable within the certified limits listed on their Confidential Statement of Formula (CSF). The storage stability analysis is **UNACCEPTABLE**, but upgradable. The registrant must:
 - a. Demonstrate the stability of each of the two ingredients that are listed as active ingredients on the Confidential Statement of Formula (CSF). Specifically, the registrant must show whether or not the nominal concentrations of these two ingredients remain above the lowest respective certified limit after 12 months of storage.
 - b. Explain those values lying outside the active ingredient certified limits for each product.
 - c. Justify why sampling for each container type was not performed at each time interval.
2. The Corrosion Characteristics analysis indicates that the test substance is not corrosive to packaging materials. The corrosion characteristics data are **ACCEPTABLE**; no additional data are required.

STUDY SUMMARIES

Storage Stability

The registrant has submitted MRID 48106201 to fulfill the Storage Stability data requirement for the manufacturing-use product (MP) Refined Oil of *Nepeta cataria* (EPA Reg No. 71654-20), and end-use products (EPs) Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21), Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23), Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24), and Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25). The study was conducted in accordance with OPPTS Guideline 830.6317 with the following deviations:

- Samples of each product were contained in glass and high density polyethylene (HDPE). Samples of the TGAI/MP were also contained in aluminum (Al). Not all container types were sampled at each time point during the study (0 months, 3 months, 6 months, etc).
- No sample reading were taken at 9 or 12 months. In lieu of a 12-month reading, the samples were read at T = 15 months.

All samples were stored at 25°C and 50% relative humidity for the duration of the study (June, 2001-October, 2008). For each analysis, three portions of the sample to be analyzed were weighted, mixed with a solution of the internal standard 1,2-dibromobenzene and analyzed via

gas chromatograph. (Standards used for calibration/comparison included nepetalactones, dihydronepetalactones, nepetalic acids, pulegic acids, and beta-caryophyllene.) Each of the triplicate samples was analyzed twice in a back to back fashion, thus giving six readings per sampling event. The six values are averaged and these results are displayed in Tables 1-5, below. Because the chromatography can be different for a sample when analyzed as prepared compared to the chromatography of the sample when diluted (sometimes the more concentrated peak will "tail" extensively and can cause the peak not to be within the desired window), all samples were analyzed as prepared, and also analyzed after dilution. The registrant states in their report (MRID 48106201) that the data for the "neat" or "as prepared" samples are reported for reference only, and should not be used in analysis due to the tailing of such peaks and the potentially erroneous GC readings they produce. Therefore, only the results from the diluted preparations are analyzed here.

BPPD has calculated the percent change in active ingredient for each sample. Samples were compared to T = 0 values, unless an analysis was not done at T = 0. Then, the percent change was calculated from the earliest recorded value. **The registrant must justify why sampling did not take place from each container type at each time interval.**

Table 1: Results for Refined Oil of *Nepeta cataria* Technical (EPA Reg No. 71654-20)[†]

| | Glass | | HDPE | | Aluminum | |
|-----------|-------|----------|-------|----------|----------|----------|
| | % AI | % change | % AI | % change | % AI | % change |
| T = 0 | 96.28 | n/a | n/d | n/a | n/d | n/a |
| T = 3 mo | n/d | n/a | 85.07 | n/a | 83.93 | n/a |
| T = 6 mo | 92.63 | -3.79 | 93.32 | 9.70 | 92.46 | 10.16 |
| T = 15 mo | 91.14 | -5.34 | 93.95 | 10.44 | 93.13 | 10.96 |

Table 2: Results for Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21)[†]

| | Glass | | HDPE | |
|-----------|-------|----------|------|----------|
| | % AI | % change | % AI | % change |
| T = 0 | 6.38 | n/a | n/d | n/a |
| T = 3 mo | n/d | n/a | 5.89 | n/a |
| T = 6 mo | n/d | n/a | 6.81 | 15.6 |
| T = 15 mo | 6.13 | -3.92 | 6.08 | 3.23 |

Table 3: Results for Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23)[†]

| | Glass | | HDPE | |
|-----------|-------|----------|-------|----------|
| | % AI | % change | % AI | % change |
| T = 0 | 14.86 | n/a | n/d | n/a |
| T = 3 mo | n/d | n/a | 13.17 | n/a |
| T = 6 mo | n/d | n/a | 15.48 | 17.54 |
| T = 15 mo | 14.07 | -5.32 | 14.41 | 9.42 |

Table 4: Results for Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24)[†]

| | Glass | | HDPE | |
|-----------|-------|----------|------|----------|
| | % AI | % change | % AI | % change |
| T = 0 | 6.32 | n/a | n/d | n/a |
| T = 3 mo | n/d | n/a | 6.19 | n/a |
| T = 6 mo | n/d | n/a | 6.87 | 10.98 |
| T = 15 mo | 6.59 | 4.27 | 6.5 | 5.01 |

Table 5: Results for Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25)[†]

| | Glass | | HDPE | |
|-----------|-------|----------|-------|----------|
| | % AI | % change | % AI | % change |
| T = 0 | 14.00 | n/a | n/d | n/a |
| T = 3 mo | n/d | n/a | 13.76 | n/a |
| T = 6 mo | n/d | n/a | 15.46 | 12.36 |
| T = 15 mo | 14.20 | 1.41 | 14.59 | 6.03 |

[†] MRID 48106201, pp 14-15.

The results for the manufacturing-use product (MP) are listed in Table 1. This product, Refined Oil of *Nepeta cataria* (EPA Reg No. 71654-20) has an active ingredient (a.i.) concentration of 100% listed on its label and two components listed as active ingredients on its CSF. **The data presented do not clearly demonstrate that the two active ingredients present in their technical grade active ingredient (TGAI) are stable within the certified limits listed on their CSF. This must be addressed.**

The end-use products (EPs) analyzed in this study were stored and sampled from glass and HDPE containers only. The results for Refined Oil of *Nepeta cataria* 7% Lotion (EPA Reg No. 71654-21) are listed in Table 2. The a.i. concentration listed on the Confidential Statement of Formula (CSF) for this product is 7.0%, with upper and lower certified limits of 7.35% and 6.65%, respectively. Measured concentrations in this study range from 5.89 to 6.81 percent a.i. Specifically, ending values (T = 15 months) are 6.13% for the glass container and 6.08% for the HDPE container. These values are below the lower certified limit for the a.i. **The registrant must explain these a.i. percentage values.**

The results for Refined Oil of *Nepeta cataria* 15% Lotion (EPA Reg No. 71654-23) are listed in Table 3. The a.i. concentration listed on the CSF for this product is 15.0%, with upper and lower certified limits of 15.75% and 14.25%, respectively. The ending concentration for the HDPE container was within these limits at 14.41%. The ending a.i. concentration for the glass container was 14.07, which is below the lower certified limit. **The registrant must explain this value.**

The results for Refined Oil of *Nepeta cataria* 7% Liquid (EPA Reg No. 71654-24) and Refined Oil of *Nepeta cataria* 15% Liquid (EPA Reg No. 71654-25) are listed in Tables 4 and 5, respectively. Both products show a net increase in a.i. concentration over the course of the study.

However, the starting concentrations of a.i. for both products was below the lower certified limit values listed on the CSF. **The registrant must explain these values.**

CLASSIFICATION: UNACCEPTABLE, but upgradable. The registrant demonstrate that the two active ingredients present in their TGAI are stable within the certified limits listed on their Confidential Statement of Formula CSF. The registrant must justify why sampling for each container type was not performed at each time interval. The registrant must also explain values lying outside the active ingredient certified limits.

Corrosion Characteristics

Observations of the samples and packaging used in the above study of Storage Stability lead the study authors to conclude that the test substance is not corrosive to packaging materials. Details of these observations were not included.

CLASSIFICATION: ACCEPTABLE, no additional data are required.

Data Evaluation Records (DERs) were not written for this review. For additional information on these Storage Stability and Corrosion Characteristics studies, please refer to MRID 481062(0)1.

cc: G. Casciano, M. Adams, R. S. Jones, BPPD Science Review File, IHAD/ARS
G. Casciano, Biologist, FT, PY-S: 8/25/2010

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

SEP 01 2010

Thomas C. McEntee
 DuPont Chemical Solutions Enterprise
 P.O. Box 80402
 Wilmington, DE 1988-0402

Subject: Refined Oil of Nepeta Cataria 7% Liquid
 EPA Registration No. 71654-24
 Storage Stability and Corrosion Characteristics
 Decision # 434660
 Application Dated: May 21, 2010

Dear Mr. McEntee:

The Storage Stability and Corrosion Characteristics Guideline study (OPPTS 830.6317 and OPPTS 830.6320) referred to above, submitted in response to the terms and conditions of registration as issued March 26, 2009, is **unacceptable but upgradeable**. The following deficiencies need to be addressed:

1. You must clearly demonstrate the stability of the two active ingredients listed on your Confidential Statement of Formula (CSF) by showing whether or not the nominal concentration of these two ingredients are within the certified limits listed on the CSF after 12 months of storage.
2. You must explain the percentage values that are below the lower certified limits for the active ingredients.
3. You must justify why sampling was not performed from each container type at each time interval.

If you have any questions contact Ms. Menyon Adams at 703-347-8496 or by email at: adams.menyon@epa.gov.

Sincerely,



Linda A. Hollis, Chief
 Biochemical Pesticides Branch
 Biopesticides and Pollution
 Prevention Division (7511P)

CONCURRENCES

| | | | | | | | | |
|----------|------------|--|--|--|--|--|--|--|
| SYMBOL | ▶ 7511P | | | | | | | |
| USERNAME | ▶ Adams | | | | | | | |
| DATE | ▶ 08/31/10 | | | | | | | |



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

71654-24

Date of Issuance:

3/26/09

NOTICE OF PESTICIDE:

 X Registration Re-registration
(under FIFRA, as amended)

Term of
Issuance:

Conditional

Name of Pesticide Product:

Refined Oil of *Nepeta cataria* 7%
Liquid Insect Repellent

Name and Address of Registrant (include ZIP Code):

DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c) (7)(A) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit within 12 months data package for Storage Stability Guideline Study (OPPTS 830.6317).
3. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 71654-25.
4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.
5. This registration is effective for 1 year from the date of issuance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Joseph L. Anderson

Date:

3/26/09

Michael McDavit, Associate Director

CONCURRENCES

| | | | | | | | |
|---------|---|--------------------|--------------------|--|--|--|----|
| SYMBOL | Biopesticides and Pollution Prevention Division | 7511P | 7511P | | | | |
| SURNAME | | <i>[Signature]</i> | <i>[Signature]</i> | | | | |
| DATE | EPA Form 8570-6 | 3/23/09 | 3/23/09 | | | | 58 |

Refined Oil of *Nepeta cataria* 7% Liquid

Insect Repellent Liquid
Insect Repellent Pump-Spray[OPT]

ACCEPTED

ACTIVE INGREDIENT:

| | |
|--|--------|
| Refined Oil of <i>Nepeta cataria</i> | 7.0% |
| Other Ingredients | 93.0% |
| Total | 100.0% |

MAR 26 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 71654-24

EPA Reg. No. 71654 – EU [24]

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves. If used on the face, spray/dispense on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Dispense/Spray apply a small amount of liquid directly onto skin. Spread uniformly to completely cover any exposed skin surface. Use sparingly on face and avoid contact with eyes. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin. After returning indoors, wash treated skin with soap and water or bathe. Also wash treated clothing before wearing it again.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing.

PHYSICAL AND CHEMICAL HAZARDS

FLAMMABLE. Keep away from Heat and Open Flame.

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

Net Contents: _____

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) (uncompromised) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Complete Outdoor protection (OPT)
- Guards the whole family (safely) (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) formula (OPT)
- Safety outdoors for play and on the go (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Frequent reapplication (and saturation) unnecessary (OPT)
- Contains (a) plant-based repellent (OPT)
- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (OPT)
- Contains plant extracts (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- For playing and relaxing outdoors (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)

- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- No residue on skin (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)

DATA PACKAGE BEAN SHEET

Date: 07-Jun-2010

Page 1 of 2

Decision #: 434660

DP #: (378696)

NON PRIA

Parent DP #:

Submission #: 875469

*** Registration Information ***

Registration: 71654-24 - REFINED OIL OF NEPETA CATARIA 7% LIQUID

Company: 71654 - E.I. DUPONT DE NEMOURS AND COMPANY

Risk Manager: RM 91 - Linda Hollis - (703) 308-8733 Room# PY1 S-8761

Risk Manager Reviewer: Menyon Adams MADAMS07

Sent Date: 27-May-2010

Calculated Due Date: 14-Sep-2010

Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (575) CONDITIONAL REGISTRATION FOLLOW-UP;DATA REQUIRED;REQUIRES SCIENCE

Ingredients: 004801, Nepeta cataria oils(7%)

*** Data Package Information ***

Expedite: ☐ Yes ☒ No

Date Sent: 07-Jun-2010

Due Back: _____

DP Ingredient: 004801, Nepeta cataria oils

DP Title: _____

CSF Included: ☒ Yes ☐ No

Label Included: ☒ Yes ☐ No

Parent DP #: _____

Assigned To

Date In

Date Out

Organization: BPPD / BPB

07-Jun-2010

Last Possible Science Due Date: 06-Jul-2010

Team Name: RM 91

07-Jun-2010

Science Due Date: _____

Reviewer Name: Jones, Russell

07-Jun-2010

Sub Data Package Due Date: _____

Contractor Name: _____

*** Studies Sent for Review ***

Printed on Page 2

*** Additional Data Package for this Decision ***

No Additional Data Packages

*** Data Package Instructions ***

Attention Russ,
Please review the storage and stability submission.
Thanks

Due Date August 16, 2010

DP#: (378696)

*** Studies Sent for Review ***

Decision#: (434660)

| MRID | MRID Status | Citation Reference | Guideline |
|----------|-------------|--|------------------------------------|
| 48106201 | | Davis, E. (2010) One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. Unpublished study prepared by E.I. du Pont de Nemours and Company. 42 p. | 830.6320/Corrosion characteristics |
| 48106200 | | E.I. du Pont de Nemours and Company (2010) Submission of Product Chemistry Data in Support of the Registrations of Refined Oil of Nepeta cataria Technical, Refined Oil of Nepeta cataria 15% Lotion, Refined Oil of Nepeta cataria 7% Lotion, Refined Oil of Nepeta cataria 15% Liquid and Refined Oil of Nepeta cataria 7% Liquid. Transmittal of 1 Study. | |
| 48106201 | | Davis, E. (2010) One Year Storage Stability Analysis and Container Corrosion Characteristics of Refined Oil of Nepeta cataria and Refined Oil of Nepeta cataria Formulations. Project Number: CCAS/200702/S04, APEX/838/04. Unpublished study prepared by E.I. du Pont de Nemours and Company. 42 p. | 830.6317/Storage stability |

Memorandum

Date: 06 / 03 / 10

To: Patricia, Regulatory Manager

From: Information Services Branch, ITRMD

Your receipt of this data submission is not an indication that MRIDs for the enclosed studies have been posted to OPPIN.

We expect that it will be approximately 5 days from the above date before the study-level data is available in OPPIN.

If you have any questions about this process, please contact Teresa Downs (305-5363).

This is a: ☒ fully accepted submission
☐ partially accepted submission
☐ rejected submission



U.S. ENVIRONMENTAL PROTECTION AGENCY
Office of Pesticide Programs
Biopesticides and Pollution Prevention Division (7511C)
1200 Pennsylvania Avenue NW
Washington, DC 20460

EPA Reg.
Number:

71654-24

Date of Issuance:

3/26/09

NOTICE OF PESTICIDE:

☒ Registration ☐ Re-registration
(under FIFRA, as amended)

Term of
Issuance:

Conditional

Name of Pesticide Product:

Refined Oil of *Nepeta cataria* 7%
Liquid Insect Repellent

Name and Address of Registrant (include ZIP Code):

DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act.

Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Sec. 3(c) (7)(A) provided you:

1. Submit and/or cite all data required for registration/ reregistration of your product under FIFRA section 3(c)(5) and section 4 when the Agency requires all registrants of similar products to submit such data.
2. Submit within 12 months data package for Storage Stability Guideline Study (OPPTS 830.6317).
3. Make the following label change before you release the product for shipment: Revise the EPA Registration Number to read, "EPA Reg. No. 71654-25.
4. Submit three (3) copies of the revised final printed labeling before you release the product for shipment.
5. This registration is effective for 1 year from the date of issuance.

If these conditions are not complied with, the registration will be subject to cancellation in accordance with FIFRA sec. 6(e). Your release for shipment of the product constitutes acceptance of these conditions. A stamped copy of the label is enclosed for your records.

Signature of Approving Official:

Josh L. Anderson

Date:

3/26/09

Michael McDavitt, Associate Director

CONCURRENCES

| | | | | | | | |
|---------|---|--------------------|--------------------|--|--|--|--|
| SYMBOL | Biopesticides and Pollution Prevention Division | 7511P | 7511P | | | | |
| SURNAME | | <i>[Signature]</i> | <i>[Signature]</i> | | | | |
| DATE | EPA Form 8570-6 | 7/23/08 | 7/26/09 | | | | |

Refined Oil of *Nepeta cataria*

7% Liquid

Insect Repellent Liquid
Insect Repellent Pump-Spray[OPT]

ACCEPTED

ACTIVE INGREDIENT:

| | |
|--|--------|
| Refined Oil of <i>Nepeta cataria</i> | 7.0% |
| Other Ingredients | 93.0% |
| Total | 100.0% |

MAR 26 2009

Under the Federal Insecticide, Fungicide,
and Rodenticide Act, as amended, for
the pesticide registered under
EPA Reg. No. 71654-24

EPA Reg. No. 71654 – EU [24]

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves. If used on the face, spray/dispense on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Dispense/Spray apply a small amount of liquid directly onto skin. Spread uniformly to completely cover any exposed skin surface. Use sparingly on face and avoid contact with eyes. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin. After returning indoors, wash treated skin with soap and water or bathe. Also wash treated clothing before wearing it again.

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

CAUTION

Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing.

PHYSICAL AND CHEMICAL HAZARDS

FLAMMABLE. Keep away from Heat and Open Flame.

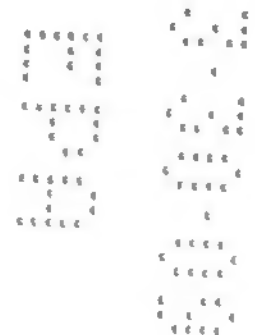
STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

Net Contents: _____

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) (uncompromised) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Complete Outdoor protection (OPT)
- Guards the whole family (safely) (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) formula (OPT)
- Safety outdoors for play and on the go (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Frequent reapplication (and saturation) unnecessary (OPT)
- Contains (a) plant-based repellent (OPT)
- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (OPT)
- Contains plant extracts (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- For playing and relaxing outdoors (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)



- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- No residue on skin (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)

3/26/09
Note: These changes
must be made
before the Agency can
approve this label

Refined Oil of *Nepeta cataria* 7% Liquid

Insect Repellent Liquid
Insect Repellent Pump-Spray[OPT]

Please
Review
per my
comment
PRN-201-3

ACTIVE INGREDIENT:

| | |
|--|--------|
| Refined Oil of <i>Nepeta cataria</i> | 7.0% |
| Other Ingredients | 93.0% |
| Total | 100.0% |

EPA Reg. No. 71654 – EU [24]

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

CAUTION

See [Back Panel][Side Panel] for Additional Precautions

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Have person sip a glass of water if able to swallow.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves. If used on the face, spray/dispense on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Dispense/Spray apply a small amount of liquid directly onto skin. Spread uniformly to completely cover any exposed skin surface. Use sparingly on face and avoid contact with eyes. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin. *after returning indoors, wash treated skin with soap and water or bathe. Also wash treated clothing before wearing it again.*

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Instant Causes moderate eye irritation. Avoid contact with eyes. Wash thoroughly with soap and water after handling. If a reaction to this product is suspected, discontinue use and take off contaminated clothing.

PHYSICAL AND CHEMICAL HAZARDS

FLAMMABLE. Keep away from Heat and Open Flame.

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

Net Contents: _____

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) (uncompromised) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Delete* • ~~Uncompromised Performance (OPT)~~
- Complete Outdoor protection (OPT)
- Guards the whole family (safely) (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Delete* • ~~Dependable Protection from Nature (OPT)~~
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) (Family) formula (OPT) → *Delete the word "Family"*
- Delete* • ~~Safety outdoors for play and on the go (OPT)~~
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Frequent reapplication (and saturation) unnecessary (OPT)
- Contains (a) plant-based repellent (OPT)
- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (OPT)
- Delete* • Contains plant extracts (OPT)
- ~~(uncompromised) (effective) (smart) Natural Protection (with Performance) (OPT)~~
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- Delete* • ~~How Nature protects (from biting insects) (OPT)~~
- Delete* • ~~(Smart) protection with confidence from nature (OPT)~~
- For playing and relaxing outdoors (OPT)

Wet

- ~~Dermatologist Tested (OPT)~~
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)
- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)

Detail

- ~~No need to wash off (OPT)~~
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- No residue on skin (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)

Wet

Detail

Raderrio
Wilkins/DC/USEPA/US
01/29/2009 01:46 PM

To Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>
cc wilkins.raderrio@epa.gov
bcc
Subject Follow up to needed label corrections for 71654-EL, and EU
(Refined Oil of Nepeta cataria)

Dear Mr. McEntee :

Please make the following revisions to you label for products 71654-EL, and EU (Refined Oil of Nepeta cataria). Attached, is a corrected label to provide guidance . Should you have questions, please contact me immediately.



scan.pdf

Sincerely,
Raderrio Wilkins
703.308.1259

Tox. Category
III. oral / primary eye
IV. acute dermal / emb. labor

Add name of
Product cat . . .

11/28/08

Refer to Label
Revision Mammie
Chapter 3, for proper
formatting
R.W.C.

ACTIVE INGREDIENT:

| | |
|--|--------|
| Refined Oil of <i>Nepeta cataria</i> | 7.0% |
| Other Ingredients | 93.0% |
| Total | 100.0% |

EPA Reg. No. 71654- *EW*

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

~~WARNING~~ *Caution*

See [Back Panel][Side Panel] for Additional Precautions

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

Net Contents: _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

~~Causes Eye Irritation. Do not get in eyes.~~

Revised:

*Make the same
corrections
to this label as
requested on product
71654-02*

*cause moderate eye irritation.
avoid contact with eyes. Wash
thoroughly with soap and water after
each handling. If a reaction to
this product is suspected, discontinue
use and take off contaminated cloth*

PHYSICAL AND CHEMICAL HAZARDS

FLAMMABLE. Keep away from Heat and Open Flame.

DIRECTIONS FOR USE — *bold*

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves. If used on the face, spray/dispense on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Dispense/Spray *apply* a small amount of liquid directly onto skin. Spread uniformly to completely cover any exposed skin surface. Use sparingly on face and avoid contact with eyes. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.

FIRST AID

Have the product container or label with you when calling a poison control center or doctor, or going for treatment.

If in Eyes:

- Hold eye open and rinse slowly and gently with water for 15-20 minutes.
- Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.
- Call a Poison Control Center or doctor for further treatment advice.

OK

If a reaction to this product is suspected:

- Discontinue use.
- Take off contaminated clothing.
- Wash skin thoroughly with plenty of water.
- Call a Poison Control Center or doctor for further treatment advice.

Remove

If Swallowed:

- Call Poison Control Center or doctor immediately for treatment advice.
- Do not induce vomiting unless told to do so by the poison control center or doctor
- Do not give anything by mouth to an unconscious person

Person

Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas).

For 24-hour transportation emergency information on this product, call Chemtrec at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas)

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

Refined Oil of *Nepeta cataria* 7% Liquid

Insect Repellent Liquid
Insect Repellent Pump-Spray[OPT]

- Mosquito repellent (OPT) ✓
- Blackfly repellent (OPT) ✓
- Repels mosquitoes (OPT) ✓
- Repels blackflies (OPT) ✓
- Effective protection from mosquitoes, biting flies (OPT) ✓
- Effectively repels mosquitoes and other biting insects (OPT) ✓
- (Effective) (uncompromised) protection (from a range of biting insects) (OPT) ✓
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (diseases) (OPT)

*Remains
wood*

- Works great on biting flies (OPT) ✓
- Protection (from bites) from biting insects (for the whole family) (OPT) ✓
- Protection for people on the go (OPT) ✓
- Protection that fits your lifestyle (OPT) ✓

*Delist
Delist*

- ~~Protection that fits a (natural, free, aware, authentic) lifestyle (OPT)~~ *Redundant language*
- ~~Protects from mosquitoes and (blackflies) (biting flies) (for over 6 hours) (OPT)~~ *Redundant language*
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)

Delist

- ~~As effective as 30% DEET in repelling mosquitoes for up to 7 hours (OPT)~~

Delist

- ~~Long-lasting effective protection against mosquitoes and other biting insects (OPT)~~

- Apply every 6 hours (or as needed) (OPT) ✓
- Repels insects for up to 7 hours (OPT) ✓
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT) ✓
- Keeps (bugs) (insects) off (your kids) (your family) (OPT) ✓
- Uncompromised Performance (OPT) ✓

*Remains
wood*

- (Natural) Complete Outdoor protection (OPT)

*Remains
wood*

- ~~(Safe)~~ Guards the whole family (safely) (OPT) ✓

- Protection that fits your (active) lifestyle (OPT) ✓
- Dependable Protection from Nature (OPT) ✓
- Protect(s) your family at dusk and dawn (OPT) ✓
- An effective broad-spectrum insect repellent (OPT) ✓
- Protection during outdoor activities (OPT) ✓
- (Sport) (Active) (Outdoor) (Family) formula (OPT) ✓
- Safety outdoors for play and on the go (OPT) ✓
- For yardwork and camping (OPT) ✓
- Protects during work, play or recreation (OPT) ✓
- Frequent reapplication (and saturation) unnecessary (OPT) ✓


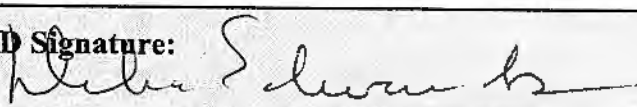
Delist

- ~~Contains a botanically-derived insect repellent (OPT)~~ ✓

- Contains (a) plant-based repellent (OPT)
- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (over 6 hours) (OPT)

- ~~Botanical(!)~~ (OPT)
- ~~New Plant based ingredient with uncompromised efficacy (repellency)~~ (OPT)
- ~~Plant based ingredient (- does not settle for less efficacy)~~ (OPT)
- Contains plant extracts (OPT)
- (uncompromised) (effective) (smart) Natural Protection (with Performance) (OPT)
- ~~(Confidence in) Natural Protection (OPT)~~ *male*

- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- ~~(Natural)~~ (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- How Nature protects (from biting insects) (OPT)
- (Smart) protection with confidence from nature (OPT)
- For playing and relaxing outdoors (OPT)
- Dermatologist Tested (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)
- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- No need to wash off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- No residue on skin (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- The safe choice (OPT)
- (Smart) (and) (safe) choice (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)

| Recommendation of Division Directors Negotiated Due Dates | | |
|---|--------------------------------------|-------------------------|
| Decision#: 541354 381354 | Registration#: 71654-EU | Petition #: N/A |
| Fee Category: B60 (PRIA 1) | PRIA Decision Time Frame: 12 months | |
| Submitted by: Raderrio Wilkins | Branch: BPB | Date: November 26, 2008 |
| Company: Dupont Chemical Solution | | |
| Original Due Date: Nov. 17, 2007 | Proposed New Due Date: Mach 31, 2009 | |
| Previous Negotiated Due Dates: 11/17/07, 5/30/08, and 11/30/08 | | |
| Is the "Fix" in-house? YES | If not, date "Fix" expected: | |
| Issue (describe in detail): In BPPD's agreement of November 8, 2007, Dupont Chemicals were to submit the following deficient data: Product Chemistry, Toxicity, and Efficacy. The Agency received the resubmitted data package in response to Agency letter dated 10/16/07 which partially addressed the Agency's concerns. To date, BPPD needs addition time to review the resubmitted data. | | |
| Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D) Product Chemistry: <u> D </u> Acute Tox: <u> D </u> Efficacy: <u> D </u> Labeling: <u> </u> Other (describe): <u> </u> | | |
| Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The company's agent (Mr. Thomas McEntee) is extremely slow in responding to Agency letters, emails and telephone messages initiated by the Regulatory Manager and Branch Chief. | | |
| "75 Day" Letter sent? <u> 9/26/07, 10/16/08 and 11/25/08 </u> (Date sent) Yes <u> </u> No and reason for none? | | |
| Note: Application was submitted under PRIA 1 | | |
| Rationale for Proposed Due Date: The resubmitted information would require BPPD Phase review of Phases III – V, which is equivalent to 6 months. | | |
| Registrant notified that this is the last negotiation? <u> X </u> Yes <u> </u> submission was submitted and <u> </u> | | |
| Approve:  | Disapprove: | |
| If disapproved, action to be taken: | | |
| OD or DOD Signature:  | | Date: 11/28/08 |



Thomas C McEntee
<Thomas.C.McEntee@usa.d
upont.com>

11/26/2008 12:44 PM

To Linda Hollis/DC/USEPA/US@EPA

cc Raderrio Wilkins/DC/USEPA/US@EPA

bcc

Subject Re: Refined Oil of Nepeta cataria -- Renegotiated PRIA
Action Dates to the calenar year 2009

Ms. Linda Hollis,

This will confirm the negotiated dates are in calenar year 2009 as you have
detailed below.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epam
ail.epa.gov

11/26/2008 12:07
PM

Thomas C McEntee/AE/DuPont@DuPont

wilkins.raderrio@epa.gov

Subject
Re: Refined Oil of Nepeta cataria
-- Renegotiated PRIA Action Dates

Thank you, but there are some errors. The dates reflect year 2008. The
dates should be the following:

71654-EN December 5, 2008

71654-EL and EU March 31, 2009

71654-EG and ER July 31, 2009 with the understanding that the Agency
may likely to renegotiate again if the the Agency is not in receipt of
all of the missing information, to include submission of the inert
information to the Registration division by February 28, 2009.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202

hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

Thomas C McEntee
<Thomas.C.McEnte
e@usa.dupont.com
>

11/26/2008 12:00
PM

To
Linda Hollis/DC/USEPA/US@EPA
cc
Raderrio Wilkins/DC/USEPA/US@EPA
Subject
Refined Oil of Nepeta cataria --
Renegotiated PRIA Action Dates

Ms. Linda Hollis,

This is to confirm our November 26, 2008 telephone conference regarding the need to renegotiate PRIA dates for the following applications for registration.

| File Symbol | Product | Date | |
|-------------|------------|------------------|--|
| 71654-EN | Technical | December 5, 2008 | (accomodate review of new active ingredient fact sheet) |
| 71654-ER | 15% Lotion | July 31, 2008 | (acquire detail from inert supplier by Feb. 28, 2009 or further renegotiate) |
| 71654-EG | 7% Lotion | July 31, 2008 | (same as 71654-EG) |
| 71654-EL | 15% Liquid | March 31, 2008 | (resolve disconnect on acute toxicology series) |
| 71654-EU | 7% Liquid | March 31, 2008 | (resolve disconnect on acute toxicology series from 71654-EL) |
| All | | | (re-review MRID 47362603 - Supplemental Efficacy Explanations; after the fact HSRB upgrades) |

If you have any questions, please feel free to call or e-mail.

Thank you for your assistance with our application.

Enjoy the Thanksgiving Holiday.

Tom McEntee
302 695 6856
978 335 8055 CELL

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

DuPont Chemical Solutions Enterprise
c/o Thomas C. McEntee
P.O. Box 80402
Wilmington, DE 1988-0402

NOV 26 2008

Re: Application for a new Biochemical pesticide Registration
Refined Oil of *Nepeta cataria*
EPA File Symbol. No. 71654-EL (15%) and 71654-EU (7%)

Dear Mr. McEntee:

The applications for Biopesticide registrations referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, has been reviewed by BPPD and are not acceptable at this time. The Product Chemistry, Product Performance and Products Specific Toxicity data are **not acceptable** for the following reason(s):

1. Product Chemistry:

- a. Storage stability (OPPTS 830.6317) and corrosion characteristics (OPPTS 830.6320) data must be submitted for both products [71654-EL (15%) and 71654-EU (7%)].
- b. The data requirement for Non-Target Organisms have not been addressed for the source of active ingredient, 71654-EN (TGAI). The data requirements must also be addressed in support of the above end use products. If your request is to bridge from the data/information that is expected to be submitted in support of the TGAI, you will need to submit a revised data matrix for both products.

2. Product Specific Toxicity data:

You have proposed to address the tier1 toxicological data requirements for the above products by the argument of bridging. That is, you have requested to bridge from product specific toxicity data conducted on the 15% lotion product (EPA File Symbol 71654-ER). This argument is not acceptable. Because the liquid spray formulations described in this letter (EPA File Symbols 71654-EL and EU) are not substantially similar in their composition to 15% lotion of which the toxicity data was originally generated, the toxicity data requirements for both products are deficient and will need to be addressed. To satisfy the toxicological data

requirement for both products (71654-EL and EU), you must generate data on each individual product or generate the data for each guideline study on the 15% liquid spray and request to bridge from that data in support of satisfying the toxicity data requirements on the 7% liquid spray formulation. In addition, you must also submit a revised data matrix for both products and indicate how you intend on satisfying the tier 1 toxicological data requirements.

3. Product Performance:

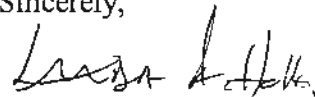
The product performance for both (-EL and -EU) are deficient. Please address the inconsistencies associated with the amount of test d to subjects. The submitted study does not explain whether the dose of active ingredient applied for testing was consistently applied among all subjects regardless of formulation type. The following ethical issues must be addressed: 1) The use of employees of Insect Control & Research in mosquito bite-testing and 2) The lack of monitoring information on local mosquito-borne vectors prior to testing.

Your application as submitted under the Pesticide Registration Improvement Act (PRIA) guaranteed you a regulatory decision for the action category (B60) of twelve months. By regulation, the Agency is obligated to give you 75 days (40 CFR 152.105) in which to address the deficiencies identified above. However, the PRIA due date of November 30, 2008 precedes 75 day date and we will need to renegotiate the due date for this product immediately. We will need to hear from you upon receipt of this letter to determine the date for renegotiation should you wish to do so. The renegotiation time frame needed for these products will be 6 months post the date the information is received in the Agency.

Alternately, you may withdraw the application and resubmit when you have all the information. If we do not hear from you, the Agency will issue a can not grant letter under PRIA 2 on or about November 30, 2008. You will still have 75 days from the date of this letter to submit the required information before the Agency would withdraw your application because it is incomplete.

If the Agency does issue a letter stating it cannot grant your application under PRIA and you submit the required information with 75 days, the Agency will continue to work on your application, but it will not be subjected to PRIA time. Please contact Mr. Raderrio Wilkins, the Regulatory Action Leader for this product immediately upon receipt of this letter at (703) 308-1259 with your response.

Sincerely,



Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460**

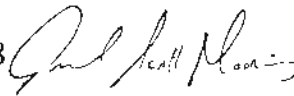
OFFICE OF PESTICIDES AND TOXIC SUBSTANCES

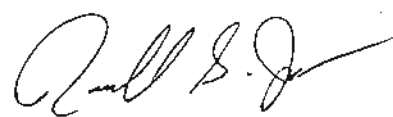
MEMORANDUM

DATE: November 25, 2008

SUBJECT: Science Review in Support of the Registration of Refined Oil of *Nepeta Cataria* 15% Liquid and Refined Oil of *Nepeta Cataria* 7% Liquid, Containing 15% and 7% Oil of *Nepeta cataria*, respectively, As Its Active Ingredients.

| | |
|---------------------------------|----------------------------------|
| Decision Number: | 381478 |
| DP Number: | 358740 |
| EPA File Symbol Numbers: | 71654-EL, 71654-EU |
| Chemical Class: | Biochemical |
| PC Code: | 004801 |
| CAS Number: | 8023-84-5 |
| Tolerance Exemptions: | n/a |
| MRID Numbers: | 471814-00, 01, 02; 474254-00, 01 |

FROM: Jacob Moore, Chemist /s/ 11/25/08 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THROUGH : Russell S. Jones, Ph.D. Senior Biologist /s/ 11/25/08 
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

TO: Raderrio Wilkins, Regulatory Action Leader
Biochemical Pesticides Branch
Biopesticides & Pollution Prevention Division (7511P)

THE FOLLOWING CONTAINS CONFIDENTIAL BUSINESS INFORMATION

ACTION REQUESTED

In response to the request for additional information relayed in a letter from BPPD to the registrant dated 08/29/07, the registrant has submitted product chemistry studies in MRIDs 47181401, 47181402, and 47425401.

RECOMMENDATIONS AND CONCLUSIONS

1. The CSFs dated 7/17/07 is acceptable, but the following is noted:
 - a. The source of the active ingredient, 71654-EN, is not yet registered. Successful registration of products 71654-EL and -EU are dependent on registration of product 71654-EN.
2. Product chemistry data for product 71654-EU is unacceptable:
 - a. Storage stability (OPPTS 830.6317) and corrosion characteristics (OPPTS 830.6320) data must be submitted.
3. Product chemistry data for product 71654-EL is unacceptable:
 - a. Storage stability (OPPTS 830.6317) and corrosion characteristics (OPPTS 830.6320) data must be submitted.

STUDY SUMMARIES

Product Chemistry (MRIDs 47181401, 47181402, and 47425401)

Refined oil of *Nepeta cataria* is a mixture of naturally-derived compounds, consisting primarily of dihydronepetalactone. Commonly known as hydrogenated catmint oil (HCO), the active ingredient in these formulations is for use as a topical insect repellent. At room temperature, the two end-use products are liquid, the difference between the two products being the concentrations of active ingredient (15% and 7%) and the concentrations of several inert ingredients, [REDACTED] MSDS were submitted for each of the inert ingredients from their respective manufacturers. The product chemistry data in these studies are satisfactory for satisfying the data requirements. However, no product chemistry data was submitted for storage stability and corrosion characteristics. Successful registration of the end-use products is dependent on these data requirements being satisfied through data or waiver rationale.

cc: J. Moore, R. Jones, R. Wilkins, BPPD Science Review File, IHAD/ARS
J. Moore, FT, PY-S: 11/25/08



Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>

11/05/2008 09:31 AM

To Linda Hollis/DC/USEPA/US@EPA
cc Raderrio Wilkins/DC/USEPA/US@EPA
bcc

Subject Re: Status of Catnip Pending product applications

Ms. Linda Hollis,

Thank you for the e-mail. I look forward to the receipt of the deficiency letters.

I have been in contact with [REDACTED] after he was able to return to his office following Hurricane Ike.

I do expect to submit a renegotiated PRIA date for the formulations which you have been handling. I'll endeavor to detail the date at which we expect to submit the information on the inert or have it submitted directly to you.

Thank you for all of your efforts with the applications and successful completion of the technical grade product.

Tom McEntee
302 695 6856
978 335 8055 CELL



Hollis.Linda@epamail.epa.gov

10/31/2008 09:06 AM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
wilkins.raderrio@epa.gov
Subject
Status of Catnip Pending product applications

Dear Mr. McEntee: I am providing to you the status of the Catnip pending applications. I do have good news and will provide that for you first. The technical product application will be registered by the priadue date of November 30, 2008. With regard to all of the he remaining end use products which will be formulated with TGA material, they are deficient and will need to be renegotiated. For some time now there has been a serious issue with regard to one of the inert components in the formulations, i.e., the proprietary blend, the components of this blend unfortunately are not cleared. We have been in communication with you earlier this year and Karen Angulo did provide you with guidance as to

how to proceed with the supplier of this blend. In fact, we do have record of contact with [REDACTED] who has provided us with information, but unfortunately, not what we need. Communication on the part of [REDACTED], did cease, and for that reason, we still are unable to process or clear the components of the blend. You will be receiving a detailed deficiency letter in the mail within the next week. However, I need to communicate to you your regulatory options. You will either need to renegotiate the due date for this products to be in line with how soon [REDACTED] will be able to make the formal request to the inerts branch as to what is needed and submit the information, in addition to addressing the data deficiencies that still remain with this products. Again, [REDACTED] is aware of what is needed and how to submit as told to him by EPA staff in the Inerts Branch. This information must come directly from the supplier. Should you not renegotiate and not make contact with the Agency, either myself or Mr. Wilkins, then we will proceed with the issuance of a can not grant letter by or on November 30, 2008. As explained to you in earlier letters, a can not grant letter will essentially put you out of a scheduled work frame, i.e., no longer *pria*. We can still work on your application, but there will be no scheduled time. Should you elect to renegotiate the date, keep in mind that Inert Clearance falls within the scope of the Registration Division. They have indicated that they will need four to five months to clear this inert, this time should be added to the amount of time that BPPD will need to conduct review (of the resubmitted information per the deficiency letter that is to come) and make a regulatory decision. Having said this, the total amount of renegotiated time will most likely be 8 months.

Your urgent response is requested.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
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(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

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Francais Deutsch Italiano Espanol Portugues Japanese Chinese Korean

Raderrio
Wilkins/DC/USEPA/US
09/30/2008 06:15 PM

To Linda Hollis/DC/USEPA/US@EPA
cc
bcc
Subject The status on the Catnip Products (71654-EG, ER, EU and EL)

Linda,

Per your request, I summarized the status of the Catnip products for your information (details listed below).

EPA File Symbol 71654-EN (TGAI):

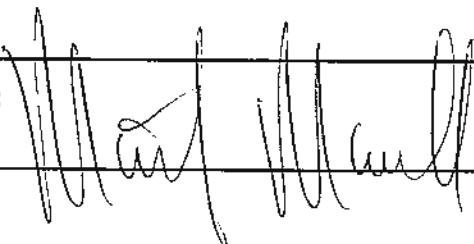
1. The registrant addressed the Product chemistry for the TGAI in MRIDs (47362601 and 47362602).
2. The registrant must submit storage stability and corrosion characteristics tests.
3. The Tier I Toxicity studies have previously been termed **ACCEPTABLE** (Gardner to Wilkins 10/04/07; Wilkins to McEntee 10/16/07). DuPont submitted a discussion (MRID 47362604) that addressed the questions EPA had regarding a positive mouse lymphoma assay. The discussion provided an **ACCEPTABLE** rationale for the TGAI being non-genotoxic and explores the concept of false test positives and weight of the evidence.
4. Although product performance data is not required for the registration of the TGAI (Refined oil of *Nepeta cataria*), however DuPont responded to the study deficiencies by submitting a supplement (MRID 47362603) to the previously submitted **UNACCEPTABLE** study. **The supplement satisfactorily addressed the scientific deficiencies present in the original studies, however ethical issues still have not been resolved and may need further review (Classification remains UNACCEPTABLE, but upgradable).**
In particular, ethical questions involve, but are not limited to:
 - 1) The use of employees of Insect Control & Research in mosquito bite-testing,
 - 2) The lack of monitoring information on local mosquito-borne vectors prior to testing,
 - 3) Other issues identified in a previous review (Fuentes to Wilkins 10/04/07).

EPA File Symbol 71654-ER and EG (EPs):

1. Product chemistry and CSF deficiencies for the 7% (71654-EG) and 15% (71654-ER) lotion have not been addressed as requested (Wilkins to McEntee, 10/16/07). I am not in receipt of any resubmission for products **71654-ER, EG, EU or EL.**

Sincerely,
Raderrio

* Unknown to BPPD until recently with the receipt of a new FAX, the Agency informed DuPont in a letter dated 10/16/07 to identify ~~all companies~~ all companies. One of the companies listed is [REDACTED]

| Recommendation of Division Directors Negotiated Due Dates | | |
|--|--|--------------------|
| Decision#: 381354 | Registration#: 71654-EU | Petition #: N/A |
| Fee Category: B60 (PRIA 1) | PRIA Decision Time Frame: 12 months | |
| Submitted by: Raderrio Wilkins | Branch: BPB | Date: May 19, 2008 |
| Company: Dupont Chemical Solution | | |
| Original Due Date: Aug. 30, 2008 | Proposed New Due Date: November 30, 2008 | |
| Previous Negotiated Due Dates: none | | |
| Is the "Fix" in-house? No | If not, date "Fix" expected: 6/13/08 | |
| Issue (describe in detail): In BPPD's agreement of November 8, 2007, Dupont Chemicals were to submit the following deficient data (refer to deficiency letter dated 10/16/07): Product Chemistry (CSF deficiencies), Change in four inerts (submit inerts substantially similar), Efficacy (submit information regarding description of studies, species etc.), and Mutagenicity Study (Point Mutag. Assay to validate or confirm results) for products 71654-EN, -ER, -EG, -EU and -EL by the end February 2008 to support the bridging of data. The Agency received the resubmitted data package in mid-March. Furthermore, the product contain four inerts in the formulation that are not cleared for use which the registrant did not address in their resubmission as outlined in the Agency's letter of October 16, 2007. Failure to submit the missing data by the end of February impacted the new Pria Date of May 30, 2008. To date, the information as resubmitted remains incomplete. | | |
| Summary of Deficiency Type(s): Not Submitted (N) Deficiencies (D) Product Chemistry: <u> D </u> Acute Tox: <u> D </u> Efficacy: <u> D </u> Labeling: <u> </u> Other (describe): <u> </u> | | |
| Describe Interactions with Company (describe when contacted and company's response including response to previous negotiated due dates): The company's agent (Mr. Thomas McEntee) is extremely uncooperative and slow in responding to Agency letters, emails and telephone messages initiated by the Regulatory Manager and Branch Chief. | | |
| "75 Day" Letter sent? <u>10/16/08</u> (Date sent) Yes <u> </u> No and reason for none? <u> </u> | | |
| Note: Application was submitted under PRIA 1 (Step-child of other Catnip products) | | |
| Rationale for Proposed Due Date: The resubmitted information would require BPPD Phase review of Phases II – V, which is equivalent to 6 months. The 180 day extension would allow the registrant time to resolve their formulation problem by change the four inert to a substantially similar chemical or submit an application for inert clearance to RD. | | |
| Registrant notified that this is the last negotiation? <u> X </u> Yes <u> </u> submission was submitted and <u> </u> | | |
| Not Applicable | | |
| Approve: <u> ✓ </u> | Disapprove: | |
| If disapproved, action to be taken: | | |
| OD or DOD Signature:  | Date: <u>5-29-08</u> | |

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402



DuPont Chemical Solutions Enterprise

May 14, 2008

Ms. Linda Hollis
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: Renegotiated PRIA Due Dates

"Refined Oil of *Nepeta cataria* Technical; EPA File Symbol 71654-EN
"Refined Oil of *Nepeta cataria*" 15% Lotion; EPA File Symbol 71654-ER
"Refined Oil of *Nepeta cataria*" 7% Lotion; EPA File Symbol 71654-EG
"Refined Oil of *Nepeta cataria*" 7% Liquid; EPA File Symbol 71654-EU
"Refined Oil of *Nepeta cataria*" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007
EPA letter of August 29, 2007
EPA letter of April 16, 2008
EPA-Dupont November 8, 2007 meeting

DuPont is accepting a renegotiated PRIA due date of November 30, 2008 which allows six months for EPA review of all of the items.

Should there be any questions, please feel free to call.

Thank you for your assistance with our applications.

Sincerely,

A handwritten signature in black ink, appearing to read "Tom McEntee", written over a horizontal line.

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695 6856

Material to be added to a Mini-Jacket (in the case where an e-Jacket exists)

Reg. No. 71654-EU

Send to SIG: check box ☐

This material is:

☐ New stamped-accepted label

☐ New CSF

☐ Notification

☐ Final Printed Label

☒ Other: RP Coverage

Instructions: Attach this notice on top of the material. It must be clipped all together and there should be NO STAPLES in the material. Then give the material with this coversheet to staff in the Information Services Center (Room 230).

Reviewer's Name: R. L. Williams

Phone: _____ Division: BPPD

Date: 5/27/06

Linda Hollis/DC/USEPA/US
05/28/2008 09:09 PM

To "Thomas C McEntee"
<Thomas.C.McEntee@usa.dupont.com>, Pv
Shah/DC/USEPA/US@EPA, Karen
cc Raderrio Wilkins/DC/USEPA/US@EPA
bcc
Subject Re: e-courtesy copy -- formal request to add inert

It has been noted that this is a courtesy copy. The Agency will act on an official copy submitted to the document processing center per my last email to you. Once submitted, the -nerts branch will determine if the information is sufficient to review.

to -----\Sent by EPA Wireless E-Mail Services.

----- Original Message -----

From: Thomas C McEntee [Thomas.C.McEntee@usa.dupont.com]
Sent: 05/28/2008 04:45 PM AST
To: Pv Shah; Karen Angulo
Cc: Linda Hollis; Raderrio Wilkins
Subject: e-courtesy copy -- formal request to add inert

Dr. PV Shah and Ms. Karen Angulo,

The attached file was expressed to IIAB today.

If you have any questions, please feel free to call or e-mail.

(See attached file: [REDACTED]
[REDACTED].pdf)

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epamail.epa.gov

05/28/2008 01:31 PM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
Wilkins.Raderrio@epamail.epa.gov,
Shah.Pv@epamail.epa.gov,
andersen.janet@epa.gov
Subject
Re: Resubmission of Information
71654 - ER and EG

Inert ingredient information may be entitled to confidential treatment

Dear Mr. McEntee:

Your application remains to be deficient and we can not proceed with review of the applications for the end use formulations with the inert clearance issue being unresolved. We renegotiated the PRIA due date for your product to reflect a date of November 2008 with the understanding that in doing so, the materials necessary for the Inerts Branch to review and possibly resolve the inerts issue were in house and were in the queue. I have learned as of yesterday in a conversation with both Karen Angulo and Prakashcha Shah (Pv Shah) of the Inerts Branch that you have not submitted a formal request or petition to have the inert reviewed for clearance. You indicated in an email to Karen Angulo information that you intended to present at the presubmission meeting scheduled for April 23, 2008. Unfortunately, you did not show up for the meeting and the Inerts Branch has to date not received any formal submission from you. It is also unclear from your email to Karen Angulo whether or not your interest lies in clearance for a food or non food use. At any rate, the email to K. Angulo, does not suffice or negate the need for you to make a formal submission. The information submitted in the email, per the Inerts group is not sufficient for them to consider, further, your request, per the Inerts Group is not currently on their schedule. In order for the Inerts Group to review your request, they will need an official/formal request/petition. The Inerts group will not add you to their schedule until your and successfully completed the following steps:

- 1) submit a formal submission (non-food) and or petition (food) to IIAB, and;
- 2) It is determined by the Inerts Group that it is sufficient to work on. When this determination is made, the Inerts group may be able to give you an estimated completion timeframe.

This missing information will affect your new due date as the time frame was calculated based on the understanding that your information had been officially submitted and was being reviewed. As a result, you will only have 75 days from the date of this email (August 11, 2008) to officially submit the above information through the EPA Document Processing Center. Failure to submit the information by August 11, 2008 will result in a can not grant for the end use applications.

Linda A. Hollis
Chief, Biochemical Pesticides Branch
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs (7511P)
U.S. Environmental Protection Agency
One Potomac Yard
2777 S. Crystal Drive
Arlington, VA 22202
hollis.linda@epa.gov
(703) 308-8733 (phone)
(703) 308-7026 (fax)
Visit <http://www.epa.gov/pesticides>

Thomas C McEntee

<Thomas.C.McEnte
e@usa.dupont.com
>

05/28/2008 10:55
AM

To
Linda Hollis/DC/USEPA/US@EPA,
Raderrio Wilkins/DC/USEPA/US@EPA
cc

Subject
Re: Resubmission of Information
71654 - ER and EG

(See attached file: 20080528 Resend cover letter inert Lotion
substitutue.pdf)

Mr. Raderrio Wilkins,

Refer to the cover letter from May 8, 2008 and the added page from EPA
DER
9/19/07. Following the November 20067 meeting with you, the formulas
were
revised to substitute chemically and functionally equivalent ingredients
which are on EPA's list with the exception of one inert. This inert is
the
subject of the submission to IIRB on April 30, 2008.

Tom McEntee
302 695 6856
978 335 8055 CELL

Hollis.Linda@epam
ail.epa.gov

To
05/13/2008 11:53
McEntee/AE/DuPont@DuPont,
AM
Thomas C
Wilkins.Raderrio@epamail.epa.gov

cc

Subject
Re: Resubmission of Information
71654-EN, ER, EG and EL

I believe that your submission was submitted late in addition to the fact that there were deficiencies outlined in our letter which you have not addresses in your resubmission. I am unclear as to your involvement with the inerts group for clearance however the information as resubitted thus far remain deficient. You may either renegotiate or we will elect to issue a can not grant. Alternatively, you can withdraw.

-----Original Message-----

From: Thomas C McEntee

To: Raderrio Wilkins

To: Linda Hollis

Sent: May 13, 2008 11:06 AM

Subject: Fw: Resubmission of Information 71654-EN, ER, EG and EL

Mr. Raderrio Wilkins,

Thank you for your telephone call. I am still trying to confirm that IIRB has received the documents on the unlisted inert from our supplier, which affect the review cycle for the end-use formulated lotions.

Returning to the previous negotiated date for the Nepeta catariaTechnical and Manufcaturng Use Product (71654- EN) [EPA letter of Nov. 8, 2007], the PRIA date was May 30, 2008. We met the target date of February 2008 for re-submission. Extension of the PRIA date out to November for the technical registration does not seem justified.

Please let me know of any developments which are a basis for your suggestion of a November date for the technical registration.

Thank you for your attention to our applications.

Tom McEntee

302 695 6856

978 335 8055 CELL

----- Forwarded by Thomas C McEntee/AE/DuPont on 05/13/2008 10:44 AM -----

Thomas C

McEntee/AE/DuPont

To

05/06/2008 05:54

Hollis.Linda@epamail.epa.gov@DUPONT

PM

_MHUB

cc

wilkins.raderrio@epa.gov

Subject

Re: Fw: Resubmission of

Information 71654-EN, ER, EG and EL

(Document link: Thomas C McEntee)

Ms. Linda Hollis,

Thank you for your e-mails. I will be completing the submissions on the end-use formulas this week.

This is to confirm that I will request a renegotiated action date for the applications in the subject family, based on the complexity and date of last submission.

"Refined Oil of Nepeta cataria Technical and Manufacturing Use Product"
EPA

File Symbol 71654-EN

"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

"Refined Oil of Nepeta cataria" 7% Liquid; EPA File Symbol 71654-EU

"Refined Oil of Nepeta cataria" 15% Liquid; EPA File Symbol 71654-EL

Reference: EPA letter of October 17, 2007

EPA letter of August 29, 2007

EPA letter of April 16, 2008

EPA-Dupont November 8, 2007 meeting

(See attached file: [REDACTED])

-----Original Message Truncated-----

to -----\Sent by EPA Wireless E-Mail Services.

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http://www.DuPont.com/corp/email_disclaimer.html

(See attached file: 20080528 Resend cover letter inert Lotion substitue.pdf) [attachment "20080528 Resend cover letter inert Lotion substitue.pdf" deleted by Thomas C McEntee/AE/DuPont]

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http://www.DuPont.com/corp/email_disclaimer.html



Karen Angulo/DC/USEPA/US

05/27/2008 03:43 PM

To Linda Hollis/DC/USEPA/US@EPA

cc Raderrio Wilkins/DC/USEPA/US@EPA, Pv
Shah/DC/USEPA/US@EPA

bcc

Subject Fw: confirmation of receipt and pre-submission conference
"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol
71654-ER "Refined Oil of Nepeta cataria" 7% Lotion; EPA
File Symbol 71654-EG

Hello Linda,

Here is the email from Tom McEntee. It appears he is interested in food and non-food approval, but this is not clear. This is what he was going to explain during the pre-submission meeting in April, but he canceled that meeting. The next thing we received from him was the email below. We need him to submit more than what he has and submit a formal request/petition. What he has sent is not sufficient for us to consider. His request is not currently on our schedule, and will not be added to our schedule until he 1) submits his formal submission (non-food) and or petition (food) to IIAB, and 2) we determine it is sufficient to work on. At that time we may be able to give you an estimated completion timeframe.

Thanks,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch (IIAB)
703-306-0404
angulo.karen@epa.gov

----- Forwarded by Karen Angulo/DC/USEPA/US on 05/27/2008 03:28 PM -----



Thomas C McEntee
<Thomas.C.McEntee@usa.d
upont.com>

05/09/2008 12:57 PM

To Karen Angulo/DC/USEPA/US@EPA

cc Raderrio Wilkins/DC/USEPA/US@EPA

Subject confirmation of receipt and pre-submission conference
"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol
71654-ER "Refined Oil of Nepeta cataria" 7% Lotion; EPA
File Symbol 71654-EG

(See attached file: [REDACTED] Letter of Authorization [REDACTED].pdf)

"Refined Oil of Nepeta cataria" 15% Lotion; EPA File Symbol 71654-ER

"Refined Oil of Nepeta cataria" 7% Lotion; EPA File Symbol 71654-EG

Hello Karen,

Can you let me know if it can be confirmed that a re-qualification has been initiated relative to the product mentioned in the above letter? Can we discuss by phone or schedule a conference to get an estimate of the time required for your branch to complete the risk assessment? Do you need any other information to link the submission to our application?

BPPD has indicated the need to allow time for your assessment, so in order to negotiate a new PRIA target date, I would like to get your estimates.

I am still trying to finalize access to confidential information for other inert ingredients for a pre-application consultation. These different ingredients would be required for completely different technology than the immediate situation with the resubmissions.

Thank you for your assistance to our applications.

Tom McEntee
302 695 6856
978 335 8055 CELL

Angulo.Karen@epamail.epa.gov

04/15/2008 12:37 PM

To
Thomas C McEntee/AE/DuPont@DuPont
cc
Shah.Pv@epamail.epa.gov,
Leifer.Kerry@epamail.epa.gov,
Samek.Karen@epamail.epa.gov,
Grinstead.Keri@epamail.epa.gov,
Martin.Kathleen@epamail.epa.gov
Subject
Re: Thank you and request for
Pre-Submission Conference.

Hello

I scheduled your pre-submission meeting for next Wednesday, April 23rd, from 1 - 2 pm. Schedules are tight and that is the best day/time of the days you proposed. If this is not convenient for you, lets try for the following week. Would you like to do this via conference call?

Thank you,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
Inert Ingredient Assessment Branch (IIAB)
703-306-0404
angulo.karen@epa.gov

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>

04/09/2008 05:25 PM

To
Karen Angulo/DC/USEPA/US@EPA
cc
Subject
Re: Thank you and request for
Pre-Submission Conference.

Karen,

Thank you for the prompt reply,

I will be in the area on April 16 and 17th. I could meet on Wed. the 16th after 2:00 or break away from the ACC-biocides Panel meeting on Thursday 17th.

Alternatively, April 22/Tuesday or April 23/Wednesday.

Thanks for your consideration.

Tom McEntee
302 695 6856
978 335 8055 CELL

Angulo.Karen@epam
ail.epa.gov

To
04/09/2008 04:49 PM
Thomas C McEntee/AE/DuPont@DuPont

cc
leifer.kerry@epa.gov,
shah.pv@epa.gov

Subject
Re: Thank you and request for
Pre-Submission Conference.

Hello,

We are happy to schedule a pre-submission meeting for you. It would be helpful if you let me know several dates that you are interested in.

Thank you,

Karen Angulo
US Environmental Protection Agency
Office of Pesticide Programs
Registration Division (7505P)
703-306-0404
angulo.karen@epa.gov

Thomas C McEntee
<Thomas.C.McEntee@usa.dupont.com>

04/09/2008 01:15 PM

Pv Shah/DC/USEPA/US@EPA, Karen Angulo/DC/USEPA/US@EPA, Kerry Leifer/DC/USEPA/US@EPA

To

cc

Subject

Thank you and request for Pre-Submission Conference.

P.V. , Karen and Kerry,

Thank you and your staffs for the very illuminating meeting yesterday, The progress you are making will be a huge help in or efforts to develop and register newer technology. The uncertainty around inerts has been a major disincentive to investing in safer, more sustainable formulas and product forms.

This e-mail is also a request for a pre-submission meeting to discuss requirements for the following three projects with inert issues:

1. Refined Oil of Nepeta cataria Insect Repellent Lotion - BPPD

(See attached file: Pages 4&8 from Nepeta Product Chem DER Nov 2007.pdf)

The proposed lotion contained several ingredients that are common in cosmetics, but apparently not in currently registered insect repellents or other formulas.. I am still refining a re-submission to address the inerts issues.

2. Self-Sanitizing Antimicrobial coating for non-food contact surfaces in food preparation and service areas.

(See attached file: cloroxpcol_final.pdf)

http://www.epa.gov/oppad001/cloroxpcol_final.pdf

We are in an advanced state of development of a formula to register for the above claim. The formula requires 4 ingredients that are presently not listed.

3. Enzymatically activated in-situ Active Ingredient

We are at a mid-point development of a new antimicrobial formulation which produces the active ingredient in-situ at the point of use. The product will be used as a hard surface disinfectant. It may also be extended to laundry sanitizer and food contact use. Food contact use would be expected to require tolerance formality. It would be very valuable understand your view of risk assessment of a new enzyme. (The active ingredient is allowed at 40 CFR 180.940 without limitation as to origin).

Please let me know your availability to meet so that we can move these three projects forward.

Thank you for your assistance.

Tom McEntee
Product Registration Manager
DuPont Chemical Solutions Enterprise
302 695 6856
978 335 8055 CELL

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[attachment "Pages 4&8 from Nepeta Product Chem DER Nov 2007.pdf"
deleted by Karen Angulo/DC/USEPA/US] [attachment "cloroxpcol_final.pdf"
deleted by Karen Angulo/DC/USEPA/US]

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Letter of Authorization .pdf



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

October 2, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

OPP Decision Number: D-381354
EPA File Symbol or Registration Number: 71654-EU
Product Name: REFINED OIL OF NEPETA CATARIA 7% LIQUID
EPA Receipt Date: 18-Jul-2007
EPA Company Number: 71654
Company Name: E.I. DUPONT DE NEMOURS AND COMPANY

BONNIE J. BIEBER
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as B60 has been reclassified as Action Code: B60.4

NEW AI;NON-FOOD USE;MICROBIAL/BIOCHEMICAL;NO FEE: LINKED TO A PRIA APPLICATION;

The fee associated with this action is \$4,200. Payment in that amount has been received. No additional payment is due.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,
Front End Processing Staff
Information Technology & Resources Management Division

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

AUG 29 2007

Mr. Thomas C. McEntee
Product Registration Manager
DuPont Chemical Solutions Enterprise
P.O. Box 80402
Wilmington, DE 19880-0402

813614 / 867
1125

RE: **Product Name: Refined Oil of Nepeta cataria (15% liquid formulation)**
EPA File Symbol: 71654-EL
Application dated: July 17, 2007
Product Name: Refined Oil of Nepeta cataria (7% liquid formulation)
EPA File Symbol: 71654-EU
Your Transmittal Letter dated: July 17, 2007
PRIA Category: B-60

Dear Mr. McEntee:

The applications referred to above, submitted in connection with the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) as amended, and the Pesticide Registration Improvement Act (PRIA) have been preliminarily screened for administrative and scientific completeness by the Biopesticides and Pollution Prevention Division (BPPD). Your submissions have failed the screen for **administrative** and **scientific** completeness for the reasons below, and therefore can not be forwarded into scientific review until all of the deficiencies are satisfied and the application is complete.

Administrative Deficiencies

1. The Application Form (EPA Form 8570-1) is absent from the paperwork in your file for EPA File Symbol 71654-EU
2. The Formulators Exemption Form (EPA Form 8570-27) is absent for both of the applications referred to above. A Formulator's Exemption form will apply once the Technical Grade of the Active Ingredient is registered (See #5).
3. In support of the application for the 7% liquid spray formulation end use product (EP, 71654-EU), you submitted two product chemistry data volumes. In addition to these data, you requested that the data (for toxicology, enforcement analytical method, summary of Physical and Chemical Properties, Storage Stability, and efficacy) as submitted for the 15% liquid spray formulation EP (EPA File 71654-EL) be used in support of the application for your 7% liquid spray EP (71654-EU). The data requirements outlined above are product specific and therefore product specific information **CONCURRENCES** provided for each end use formulation. The

| | | | | | | | |
|---------|----------|--|--|--|--|--|--|
| SYMBOL | 7511P | | | | | | |
| SURNAME | Peterman | | | | | | |
| DATE | 8/29/07 | | | | | | |

110

argument or rationale to bridge from the data generated on the 15% liquid EP to the 7% liquid EP will only be considered if the formulations are very similar and similar in the sense that the inerts in both formulations are essentially the same.

With regard to the 15% liquid EP, the data have not yet been reviewed (due to deficiencies as noted in this letter). Either you must provide a complete set of data to support the application for the 7% liquid EP (71654-EU) or, if applicable, await the result of BPPD's review of data and registration of the 15% liquid EP.

4. The data matrices, for both submissions referenced above, indicate that certain guideline requirements are not applicable. This may be true for your particular application. However, please note that if you mean for any of these requirements to be waived from the requirement of guideline data, you will need to include with your application data waiver requests with a separate scientifically sound rationale to justify each request.
5. For both of the applications cited above, your request to bridge from toxicity data submitted on the now pending technical grade active ingredient (TGAI, EPA File: 71654-EN) will be considered an acceptable approach once the TGAI is federally registered.

Scientific Deficiencies

1. For 71654-EU, As indicated in the Administrative Deficiencies (number 3 above), all applications for registration must address all Tier I data requirements (product chemistry, toxicology and non-target organism, fate and expression) for biochemical pesticides per 40 CFR 158.690. These data requirements must be addressed either with the submission of data or with a request to waive testing justified by a valid scientific rationale or by stating that the study is not applicable.
2. For 71654-EU, only part of the chemistry data were submitted with this submission.
3. For both 71654-EU and -EL, the irritation and immune responses to the formulations may require further testing since the proposed use is directed to be applied to humans.
4. For 71654-EU and -EL, the submission does not include product specific efficacy data.

At this time, you may either withdraw the applications (for 71654-EL and -EU) to later submit anew once the TGAI is registered, or these applications will remain in a pending status until the time when the TGAI is registered to allow the Agency to rely on the data submitted in support of the TGAI.

Should you elect to not withdraw, you must do the following: (1) address all of the deficiencies pertinent to each formulation as outlined in this letter and resubmit, (2) once resubmitted and you have passed and the data are 86-5 compliant, you must renegotiate the due date.

Currently there is no established PRIA due date for these products since we are not yet in receipt of payment.

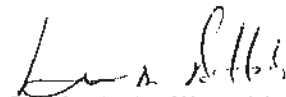
Due to the deficiencies outlined in this letter, the pending status of the technical, and the time that it will take for you to resubmit, you will likely need to renegotiate the due date once a date is established.

Because you are relying on the parent (TGAI) which is not yet registered, the negotiated time frame will be based on two factors: (a) the date that you resubmit the materials, and (b) the due date of the TGAI.

You should note however, that if there are deficiencies associated with the TGAI application, the due date and/or completion of review and regulatory decision for these applications may ultimately be affected, since these formulations can not be reviewed in their entirety until the TGAI is federally registered.

Please contact me immediately with your response by phone, (703) 308-8733, or by e-mail: hollis.linda@epa.gov.

Sincerely,



Linda A. Hollis, Chief
Biochemical Pesticides Branch
Biopesticides and Pollution Prevention
Division (7511P)

NEW APPLICATIONS

DATE: 7/18/07

FILE NUMBER: 71654-EU

FEP (OPPIN ENTRY) AC 7/18/07
(Initial & date)

FILE ROOM: _____
(Initial & date)

SIG: DS 7/23/07
(Initial & date)

FILE ROOM: JW 7-24-07
(Initial & date)

☒ ASSIGN TO PM 91 (NO DATA)

☐ JACKET TO SHELF (DATA)



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

July 19, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-381354
EPA File Symbol or Registration Number: 71654-EU
Product Name: REFINED OIL OF NEPATA CATARIA 7%LIQUID
EPA Receipt Date: 18-Jul-2007
EPA Company Number: 71654
Company Name: E.I. DUPONT DE NEMOURS AND COMPANY

Thomas McEntee
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action has been identified as Action Code: B67

NEW PRODUCT;NON-FAST TRACK;MICROBIAL/BIOCHEMICAL;

Please remit payment in the amount of: \$ 4,200 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:

U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

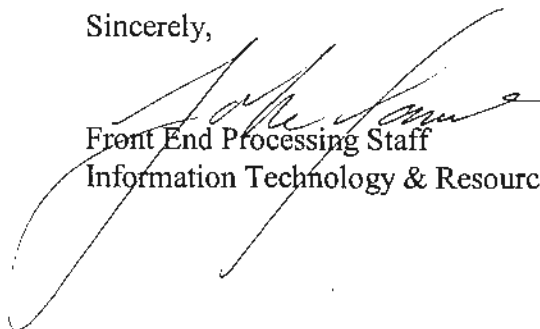
By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division

Fee for Service

81364E

~~100~~

This package includes the following

New Registration
Amendment

✓ Studies? Fee Waiver?
volpay % Reduction: ____

for Division

AD
• BPPD
RD

Risk Mgr.

☒ 91

Receipt No.

S-

~~81364~~ 813614

EPA File Symbol/Reg. No.

71654-EL

Pin-Punch Date:

7/18/2007

☐

This item is NOT subject to FFS action.

Action Code:

Requested:

B67

Granted:

B67

Amount Due: \$ ~~15,750~~ 4,200 LC

Parent/Child Decisions:

Inert Cleared for Intended Use

Uncleared Inert in Product

Reviewer: L Cole

Date: 7/19/07

Remarks:

~~New product pending registration~~

New product pending registration of new A.I. currently under review 7/19/07

FEE FOR SERVICE



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

*File
copy*

July 27, 2007

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

PLEASE RETURN A COPY OF THIS LETTER WITH PAYMENT
Or Pay On-Line at www.Pay.Gov (See Below for Details)

OPP Decision Number: D-381354
EPA File Symbol or Registration Number: 71654-EU
Product Name: REFINED OIL OF NEPETA CATARIA 7% LIQUID
EPA Receipt Date: 18-Jul-2007
EPA Company Number: 71654
Company Name: E.I. DUPONT DE NEMOURS AND COMPANY

NANCY B. LOMAX
E.I. DUPONT DE NEMOURS AND COMPANY
DUPONT CHEMICAL SOLUTIONS ENTERPRISE
PO Box 80402
WILMINGTON, DE 19880-0402

SUBJECT: Receipt of Registration Application Subject to Registration Service Fee - Revised

Dear Registrant:

The Office of Pesticide Programs has received your application for registration. If you submitted data with this application, the results of the PRN-86-5 screen will be communicated separately. During the administrative screen, the Office of Pesticide Programs has determined that this Action is subject to a Pesticide Registration Service Fee as defined in the Pesticide Registration Improvement Act.

The Action previously identified as B67 has been reclassified as Action Code: B60

NEW AI;NON-FOOD USE;MICROBIAL/BIOCHEMICAL;

Please remit payment in the amount of: \$ 15,750 to:

By USPS:
USEPA Washington Finance Center
Pesticide Registration Service Fee
PO Box 360277
Pittsburgh, PA 15251

By Courier:

U.S. EPA Washington Finance Center
Pesticide Registration Service Fee
C/O Mellon Client Service Center
500 Ross Street, Room 670
Box 360277
Pittsburgh, PA 15251-6277
Attn: EPA Module Supervisor
Telephone: (412) 236-2294

All payments must be in United States currency by check, bank draft, or money order drawn to the order of the Environmental Protection Agency. To ensure proper credit, please write the OPP DECISION NUMBER on your check, and enclose a copy of this letter with your payment.

Effective November 1, 2006, fees may be paid on-line via credit card or electronic fund transfer. To submit a payment on-line, visit www.pay.gov. From the pay.gov home page, select "search by form name." From the next page, select "P," then click on "Pesticide Registration Improvement Act. Fee Payment" and complete the form, making certain to use the decision number and registration number on the invoice you receive from the Pesticide Program in the space provided.

You may be eligible for a full or partial waiver of the registration service fee if, for example, you qualify as a small business or are applying for a minor use, or if your application is solely associated with an IR-4 tolerance petition. Please be advised that if you intend to request a waiver, you must do so in writing within 15 days of receipt of this invoice instead of remitting the amount indicated above. OPP will not consider waiver requests after the registration service fee has been paid. Information regarding eligibility and how to request and document a fee waiver is available on the OPP Fee for Service web site at www.epa.gov/pesticides/fees.

Please send Registration Service Fee Waiver requests to:

By USPS:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

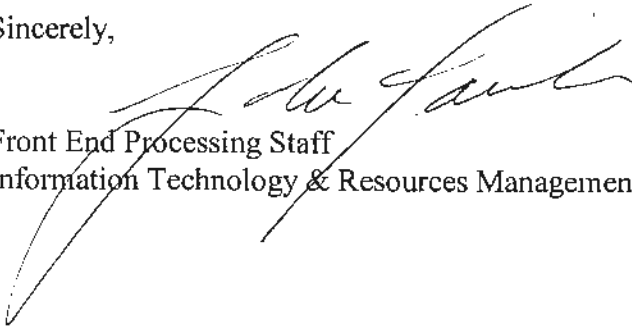
By Courier:

Document Processing Desk (WAIVER)
Office of Pesticide Programs (7504C)
U.S. Environmental Protection Agency
Room S4900 Potomac Yard 1
2777 S. Crystal Dr.
Arlington, VA 22202

A PRIA decision time review period will not start until a fee waiver is granted and/or the Agency receives certification that the outstanding fee has been paid. If the Agency does not receive certification of payment for this action or a fee waiver request within the next 45 days, the Agency will presume that you no longer want to pursue this action. The Agency will then initiate a process that may result in administrative withdrawal of this action.

If you have any questions, please contact the Pesticide Registration Service Fee Ombudsman at (703) 308-8260.

Sincerely,



Front End Processing Staff
Information Technology & Resources Management Division

8/36/14

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402



DuPont Chemical Solutions Enterprise

July 17, 2007

Mr Raderrio Wilkins
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: New Pesticide Application for Registration End-Use Insect Repellent
"Refined Oil of *Nepeta cataria* 7% Liquid"
EPA File Symbol : 71654-

This letter and its attachments comprise DuPont's application for registration of a new insect repellent end-use product, **Refined Oil of *Nepeta cataria* 7% Liquid**. There is a companion application for a new , technical grade of active ingredient and manufacturing-use concentrate, **EPA File Symbol 71654-EN**, which contains the required data of the Active Ingredient.

Besides the **Refined Oil of *Nepeta cataria* 7% Liquid**, a substantially similar end-use formulation which contains **15% Refined Oil of *Nepeta cataria***, has been submitted simultaneously.

In support of the application, the documents identified on the attached transmittal document are included.

Should there be any questions, please feel free to call.

Sincerely,

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695 6856

Products
- ER = 15%
AI
- EN = 100%
Tech
- EG = 7%

DuPont Chemical Solutions Enterprise
P. O. Box 80402
Wilmington, DE 19880-0402

-ER 15%
-EN Tech.
CC 7%



DuPont Chemical Solutions Enterprise

July 17, 2007

Mr Raderio Wilkins
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Subject: New Pesticide Application for Registration End-Use Insect Repellent
"Refined Oil of *Nepeta cataria* 7% Liquid"
EPA File Symbol : 71654-

Please find the attached Certification 8570-34 which was inadvertently omitted from the subject application.

Should there be any questions, please feel free to call.

Sincerely,

A handwritten signature in dark ink, appearing to read "Thomas C. McEntee".

Thomas C. McEntee
Product Registration Manager
Thomas.C.McEntee@usa.dupont.com
(302) 695 6856

TRANSMITTAL DOCUMENT

Attention:

Document Processing Desk (REGFEE)
Biopesticides and Pollution Prevention Division (BPPD)
US Environmental Protection Agency
Office of Pesticide Programs (7504P)
Room S-4900, One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

NAME AND ADDRESS OF SUBMITTER

E.I. du Pont de Nemours and Company
DuPont Chemical Solutions Enterprise
Experimental Station (ESL 402/3442A)
P. O. Box 80402
Wilmington, DE 19880-0402

REGULATORY ACTION IN SUPPORT OF WHICH THIS PACKAGE IS SUBMITTED-

Application for New Pesticide Registration End-Use Product

Refined oil of *Nepeta cataria* 7% Liquid; EPA File Symbol 71654-

Transmittal Date: **July 17, 2007**

Transmittal Material:

Volume 1 Administrative Materials

| | |
|--|---------|
| - Cover Letter | 1 page |
| - Application for Pesticide Registration (EPA Form 8570-1) | 1 page |
| - Transmittal Document | 1 pages |
| - CSF (EPA Form 8570-4), May 2007 | 1 page |
| - Data Matrix EPA form (8570-35) | 2 pages |
| - Certification Data Citation (8570-34) | 1 page |
| - Five copies of labeling | 4 pages |

Volume 2A Chemistry

Identity and Composition of 15% Refined Oil of *Nepeta cataria* Liquid Formulation; OPPTS 880.1100, 880.1200 and 880.1400; Pelaez, Yesinia and McEntee, Thomas; May 1, 2007. 10 pages

Volume 2B Chemistry (Cont.)

Physical and Chemical Characteristics of Refined Oil of *Nepeta cataria* 7% (w/w) liquid formulation 1630704A: Physical State, Flammability, pH, Viscosity and Relative Density; Sinning, David; Case Consulting Laboratories; Study No. 3280-32; April 17, 2007. 7 pages



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 1.25 hours per response for registration and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the completed form to this address.

Certification with Respect to Citation of Data

| | |
|--|---|
| Applicant's/Registrant's Name, Address, and Telephone Number E.I. duPont de Nemours and Company, P. O. box 80402, Wilmington, DE 19880 (302) 695 6856 | EPA Registration Number/File Symbol 71654- |
| Active Ingredient(s) and/or representative test compound(s) Refined Oil of Nepeta cataria | Date July 14, 2007 |
| General Use Pattern(s) (list all those claimed for this product using 40 CFR Part 158) Insect Repellent, Human Use | Product Name Refined Oil of Nepeta cataria 7% Liquid |

NOTE: If your product is a 100% repackaging of another purchased EPA-registered product labeled for all the same uses on your label, you do not need to submit this form. You must submit the Formulator's Exemption Statement (EPA Form 8570-27).

☐ I am responding to a Data-Call-In Notice, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose).

SECTION I: METHOD OF DATA SUPPORT (Check one method only)

| | |
|--|---|
| <input type="checkbox"/> I am using the cite-all method of support, and have included with this form a list of companies sent offers of compensation (the Data Matrix form should be used for this purpose). | <input checked="" type="checkbox"/> I am using the selective method of support (or cite-all option under the selective method), and have included with this form a completed list of data requirements (the Data Matrix form must be used). |
|--|---|

SECTION II: GENERAL OFFER TO PAY

[Required if using the cite-all method or when using the cite-all option under the selective method to satisfy one or more data requirements]

☐ I hereby offer and agree to pay compensation, to other persons, with regard to the approval of this application, to the extent required by FIFRA.

SECTION III: CERTIFICATION

I certify that this application for registration, this form for reregistration, or this Data-Call-In response is supported by all data submitted or cited in the application for registration, the form for reregistration, or the Data-Call-In response. In addition, if the cite-all option or cite-all option under the selective method is indicated in Section I, this application is supported by all data in the Agency's files that (1) concern the properties or effects of this product or an identical or substantially similar product, or one or more of the ingredients in this product; and (2) is a type of data that would be required to be submitted under the data requirements in effect on the date of approval of this application if the application sought the initial registration of a product of identical or similar composition and uses.

I certify that for each exclusive use study cited in support of this registration or reregistration, that I am the original data submitter or that I have obtained the written permission of the original data submitter to cite that study.

I certify that for each study cited in support of this registration or reregistration that is not an exclusive use study, either: (a) I am the original data submitter; (b) I have obtained the permission of the original data submitter to use the study in support of this application; (c) all periods of eligibility for compensation have expired for the study; (d) the study is in the public literature; or (e) I have notified in writing the company that submitted the study and have offered (i) to pay compensation to the extent required by sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA; and (ii) to commence negotiations to determine the amount and terms of compensation, if any, to be paid for the use of the study.

I certify that in all instances where an offer of compensation is required, copies of all offers to pay compensation and evidence of their delivery in accordance with sections 3(c)(1)(F) and/or 3(c)(2)(B) of FIFRA are available and will be submitted to the Agency upon request. Should I fail to produce such evidence to the Agency upon request, I understand that the Agency may initiate action to deny, cancel or suspend the registration of my product in conformity with FIFRA.

I certify that the statements I have made on this form and all attachments to it are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

| | | |
|---------------|-----------------------|--|
| Signature | Date July 14, 2007 | Typed or Printed Name and Title Thomas C. McEntee/ Product Registration Manager |
|---------------|-----------------------|--|



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
1200 Pennsylvania Avenue, N.W.
WASHINGTON, D.C. 20460

Form Approved OMB Nos. 2070-0060; 2070-0057;
2070-0107; 2070-0122; 2070-0164

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reviewing the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, Collection Strategies Division (2822T), U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| | | |
|---|--------------------------------|---|
| Date 07/17/2007 | EPA Reg No./File Symbol 71654- | Page 1 of 2 |
| Applicant's/Registrant's Name & Address E. I. du Pont de Nemours and Company; ESL 402/3224A P.O. Box 80402 Wilmington, DE 19880-0402 | | Product Refined Oil of Nepeta cataria 7% Liquid |

Ingredient Refined Oil of Nepeta cataria

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|-------------------------------|--|-------------|------------------------|--------|------------|
| 870.1100 | Acute Oral Toxicity | | E.I du Pont de Nemours | own | Co-Applied |
| 870.1200 | Acute Dermal Toxicity | | E.I du Pont de Nemours | own | Co-Applied |
| 870.1300 | Acute Inhalation Toxicity | | E.I du Pont de Nemours | own | Co-Applied |
| 870.2400 | Primary Eye Irritation | | E.I du Pont de Nemours | own | Co-Applied |
| 870.2500 | Primary Dermal Irritation | | E.I du Pont de Nemours | own | Co-Applied |
| 870.2600 | Dermal Sensitization | | E.I du Pont de Nemours | own | Co-Applied |
| 830.1100 | Product Identity and Composition | | E.I du Pont de Nemours | own | Attached |
| 830.1200 | Starting Materials, Production and Formulation | | E.I du Pont de Nemours | own | Attached |
| 880.1400 | Discussion of Formation of Impurities | | E.I du Pont de Nemours | own | Attached |
| 830.1800 | Enforcement Analytical Method | 47003302 | E.I du Pont de Nemours | own | 71654-ER |
| 830.1750 | Certified Limits | | E.I du Pont de Nemours | own | Attached |
| 830. | Summary Physical & Chemical Properties | | E.I du Pont de Nemours | own | Co-Applied |
| .6303, 7000, 6315, 7100, 7300 | Phys.State, Flammability, pH, Viscosity, Density | | E.I du Pont de Nemours | own | Attached |
| 830.6317 | Stability (Interim) | 46977312 | E.I du Pont de Nemours | own | 71654-ER |
| 810.3400 | Efficacy : Black Flies in Maine | 47015602 | E.I du Pont de Nemours | OWN | 71654-EN |

| | | |
|---|---|--------------------|
| Signature  | Name and Title Thomas C. McEntee, Product Registration Manager | Date 07/17/2007 |
|---|---|--------------------|



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
401 M Street, S.W.
WASHINGTON, D.C. 20460

Form Approved OMB No. 2070-0060

Paperwork Reduction Act Notice: The public reporting burden for this collection of information is estimated to average 0.25 hours per response for registration activities and 0.25 hours per response for reregistration and special review activities, including time for reading the instructions and completing the necessary forms. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden to: Director, OPPE Information Management Division (2137), U.S. Environmental Protection Agency, 401 M Street, S.W., Washington, DC 20460. Do not send the form to this address.

DATA MATRIX

| | | |
|---|--------------------------------|--|
| Date 5/16/2007 | EPA Reg No./File Symbol 71654- | Page 2 of 2 |
| Applicant's/Registrant's Name & Address E. I. du Pont de Nemours and Company; ESL 402/3224A P.O. Box 80402 Wilmington, DE 19880-0402 | | Product Refined Oil of Nepeta cataria 7% Liquid |

Ingredient Refined Oil of Nepeta cataria

| Guideline Reference Number | Guideline Study Name | MRID Number | Submitter | Status | Note |
|----------------------------|---|-------------|-------------------------------------|-------------|----------------|
| 810.3400 | Efficacy: Mosquitoes Maine | 46977424 | E.I. duPont de Nemours and Company | OWN | 71654-EN |
| 810.3400 | Efficacy: Mosquitoes Florida | 46977425 | E.I. duPont de Nemours and Company | OWN | 71654-EN |
| 40 CFR 26.1303 | Documentation of Ethical Conduct- Black flies Maine | 47113801 | E. I. duPont de Nemours and Company | OWN | 47015602 Suppl |
| 40 CFR 26.1303 | Documentation of Ethical Conduct- Mosquitoes Maine | 47113802 | E. I. duPont de Nemours and Company | OWN | 46977424 Suppl |
| 40 CFR 26.1303 | Documentation of Ethical Conduct - Mosquitoes Florida | 47113803 | E. I. duPont de Nemours and Company | OWN | 46977425 Suppl |
| 850.2100 | Avian Acute Oral Toxicity | | E. I. duPont de Nemours and Company | Not Applica | Not Applicable |
| 850.2200 | Avian Dietary Toxicity | | E. I. duPont de Nemours and Company | Not Applica | Not Applicable |
| 850.1075 | Freshwater Acute Fish Toxicity | | E. I. duPont de Nemours and Company | Not Applica | Not Applicable |
| 850.1010 | Freshwater Aquatic Invertebrate Tox | | E. I. duPont de Nemours and Company | Not Applica | Not Applicable |
| 850.4100 | Terrestrial Plant Toxicity Seedling | | E. I. duPont de Nemours and Company | Not Applica | Not Applicable |
| 850.4150 | Terrestrial Plant Toxicity Vegetative | | E. I. duPont de Nemours and Company | Not Applica | Not Applicable |
| 880.4350 | Non-Target Insect Testing | | E. I. duPont de Nemours and Company | Not Applica | Not Applicable |
| 810.3400 Supplement | NON-Guideline | | E. I. du Pont de Nemours | OWN | Co-Applicable |
| | | | | | |
| | | | | | |

| | | |
|---------------|---|--------------------|
| Signature | Name and Title Thomas C. McEntee, Product Registration Manager | Date 05/16/2007 |
|---------------|---|--------------------|

Refined Oil of *Nepeta cataria*
7% Liquid

Insect Repellent Liquid
Insect Repellent Pump-Spray[OPT]

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) (uncompromised) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (diseases) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protection that fits a (natural, free, aware, authentic) lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for over 6 hours) (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- As effective as 30% DEET in repelling mosquitoes for up to 7 hours (OPT)
- Long lasting effective protection against mosquitoes and other biting insects (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Uncompromised Performance (OPT)
- (Natural) Complete Outdoor protection (OPT)
- (Safe) Guards the whole family (safely) (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Dependable Protection from Nature (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) (Family) formula (OPT)
- Safety outdoors for play and on the go (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Frequent reapplication (and saturation) unnecessary (OPT)
- Contains a botanically-derived insect repellent (OPT)

- Contains (a) plant-based repellent (OPT)
- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (over 6 hours) (OPT)
- Botanical(!) (OPT)
- New Plant based ingredient with uncompromised efficacy (repellency) (OPT)
- Plant based ingredient (– does not settle for less efficacy) (OPT)
- Contains plant extracts (OPT)
- (uncompromised) (effective) (smart) Natural Protection (with Performance) (OPT)
- (Confidence in) Natural Protection (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Natural) (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- How Nature protects (from biting insects) (OPT)
- (Smart) protection with confidence from nature (OPT)
- For playing and relaxing outdoors (OPT)
- Dermatologist Tested (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)
- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- No need to wash off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- No residue on skin (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- The safe choice (OPT)
- (Smart) (and) (safe) choice (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)

ACTIVE INGREDIENT:

| | |
|--|--------|
| Refined Oil of <i>Nepeta cataria</i> | 7.0% |
| Other Ingredients | 93.0% |
| Total | 100.0% |

EPA Reg. No. 71654-

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

WARNING

See [Back Panel][Side Panel] for Additional Precautions

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

Net Contents: _____

PRECAUTIONARY STATEMENTS

HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes Eye Irritation. Do not get in eyes.

PHYSICAL AND CHEMICAL HAZARDS

FLAMMABLE. Keep away from Heat and Open Flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves. If used on the face, spray/dispense on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Dispense/Spray[OPT] a small amount of liquid directly onto skin. Spread uniformly to completely cover any exposed skin surface. Use sparingly on face and avoid contact with eyes. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.

| FIRST AID |
|--|
| Have the product container or label with you when calling a poison control center or doctor, or going for treatment. |
| If in Eyes: <ul style="list-style-type: none">• Hold eye open and rinse slowly and gently with water for 15-20 minutes.• Remove contact lenses, if present, after 5 minutes, then continue rinsing eye.• Call a Poison Control Center or doctor for further treatment advice. |
| If a reaction to this product is suspected: <ul style="list-style-type: none">▪ Discontinue use.• Take off contaminated clothing.• Wash skin thoroughly with plenty of water .• Call a Poison Control Center or doctor for further treatment advice. |
| If Swallowed: <ul style="list-style-type: none">• Call Poison Control Center or doctor immediately for treatment advice.• Do not induce vomiting unless told to do so by the poison control center or doctor• Do not give anything by mouth to an unconscious person |
| Emergency Contact Number: 1-800-3637(US & Canada) or 1-302-774-1139 (all other areas). |
| For 24-hour transportation emergency information on this product, call Chemtree at 1-800-424-9300 (US Canada, Puerto Rico, & Virgin Islands); 1-703 527-3887 (all other areas) |

STORAGE AND DISPOSAL

Do not contaminate water or food by storage or disposal. Store away from children.

Container Disposal: If empty, place in trash. **If partly filled:** Call your local solid waste agency or 1-800-CLEANUP for disposal instructions. Never place unused product down any indoor or outdoor drain

Refined Oil of *Nepeta cataria*
7% Liquid

Insect Repellent Liquid
Insect Repellent Pump-Spray[OPT]

- Mosquito repellent (OPT)
- Blackfly repellent (OPT)
- Repels mosquitoes (OPT)
- Repels blackflies (OPT)
- Effective protection from mosquitoes, biting flies (OPT)
- Effectively repels mosquitoes and other biting insects (OPT)
- (Effective) (uncompromised) protection (from a range of biting insects) (OPT)
- Repels mosquitoes that may carry (West Nile Virus) (Eastern Equine Encephalitis) (diseases) (OPT)
- Works great on biting flies (OPT)
- Protection (from bites) from biting insects (for the whole family) (OPT)
- Protection for people on the go (OPT)
- Protection that fits your lifestyle (OPT)
- Protection that fits a (natural, free, aware, authentic) lifestyle (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for over 6 hours) (OPT)
- Protects from mosquitoes and (blackflies) (biting flies) (for up to 7 hours) (OPT)
- As effective as 30% DEET in repelling mosquitoes for up to 7 hours (OPT)
- Long lasting effective protection against mosquitoes and other biting insects (OPT)
- Apply every 6 hours (or as needed) (OPT)
- Repels insects for up to 7 hours (OPT)
- (Smart) Outdoor protection (from annoying (mosquitoes) (biting flies) (black flies) (for up to 7 hours) (OPT)
- Repels flies (too!) (OPT)
- Keeps (bugs) (insects) off (your kids) (your family) (OPT)
- Uncompromised Performance (OPT)
- (Natural) Complete Outdoor protection (OPT)
- (Safe) Guards the whole family (safely) (OPT)
- Protection that fits your (active) lifestyle (OPT)
- Dependable Protection from Nature (OPT)
- Protect(s) your family at dusk and dawn (OPT)
- An effective broad-spectrum insect repellent (OPT)
- Protection during outdoor activities (OPT)
- (Sport) (Active) (Outdoor) (Family) formula (OPT)
- Safety outdoors for play and on the go (OPT)
- For yardwork and camping (OPT)
- Protects during work, play or recreation (OPT)
- Frequent reapplication (and saturation) unnecessary (OPT)
- Contains a botanically-derived insect repellent (OPT)

- Contains (a) plant-based repellent (OPT)
- Plant based repellent repels (mosquitoes) (and) (biting flies) (blackflies) for (up to 7 hours) (over 6 hours) (OPT)
- Botanical(!) (OPT)
- New Plant based ingredient with uncompromised efficacy (repellency) (OPT)
- Plant based ingredient (– does not settle for less efficacy) (OPT)
- Contains plant extracts (OPT)
- (uncompromised) (effective) (smart) Natural Protection (with Performance) (OPT)
- (Confidence in) Natural Protection (OPT)
- Contains the insect repellent found in (catmint) (catnip) (oil) (OPT)
- (Natural) (Plant based) (insect repellent without trade offs) (OPT)
- Always carry (product name) (OPT)
- How Nature protects (from biting insects) (OPT)
- (Smart) protection with confidence from nature (OPT)
- For playing and relaxing outdoors (OPT)
- Dermatologist Tested (OPT)
- Not oily, greasy or sticky (OPT)
- No added fragrance (OPT)
- Contains no dyes (or added fragrances) (OPT)
- No chemical odor (OPT)
- No synthetic odor (OPT)
- No unpleasant odor (OPT)
- Leaves pleasant feeling on skin (OPT)
- Won't stain (OPT)
- (Readily) (Easily) washed off (OPT)
- No need to wash off (OPT)
- Won't harm plastics (OPT)
- Specially formulated to (feel) (and) (smell) better on your skin (OPT)
- (light) (gentle) (clean) (mild) (smooth) (non-greasy) (pleasant) (feels great) (comfortable) formula (OPT)
- No residue on skin (OPT)
- (it's) pleasant smelling (OPT)
- feel's comfortable (OPT)
- DEET free (OPT)
- Non DEET (OPT)
- Non synthetic (OPT)
- The safe choice (OPT)
- (Smart) (and) (safe) choice (OPT)
- Readily washed off (OPT)
- New! (OPT)
- Sweat Resistant! (OPT.)

ACTIVE INGREDIENT:

| | |
|--|--------|
| Refined Oil of <i>Nepeta cataria</i> | 7.0% |
| Other Ingredients | 93.0% |
| Total | 100.0% |

EPA Reg. No. 71654-

EPA Est. No. XXXXX-YY-ZZZ

KEEP OUT OF REACH OF CHILDREN

WARNING

See [Back Panel][Side Panel] for Additional Precautions

Manufactured By:
E.I. du Pont de Nemours and Company
PO Box 80402
Wilmington, DE 19880-0402

Net Contents: _____

PRECAUTIONARY STATEMENTS
HAZARDS TO HUMANS AND DOMESTIC ANIMALS

Causes Eye Irritation. Do not get in eyes.

PHYSICAL AND CHEMICAL HAZARDS
FLAMMABLE. Keep away from Heat and Open Flame.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Do not allow children to handle the product or apply it to themselves. If used on the face, spray/dispense on hands first and then apply sparingly and avoid eyes. Do not spray directly onto face.

Dispense/Spray[OPT] a small amount of liquid directly onto skin. Spread uniformly to completely cover any exposed skin surface. Use sparingly on face and avoid contact with eyes. Reapplication after six hours may be necessary. When applying to children, dispense into an adults hand and then spread evenly and completely over the child's exposed skin taking care not to contact the child's fingers and hands.

Do not apply over cuts or damaged skin.

| FIRST AID |
|---|
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